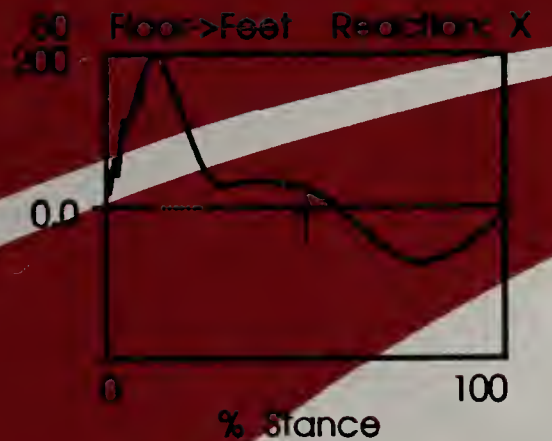
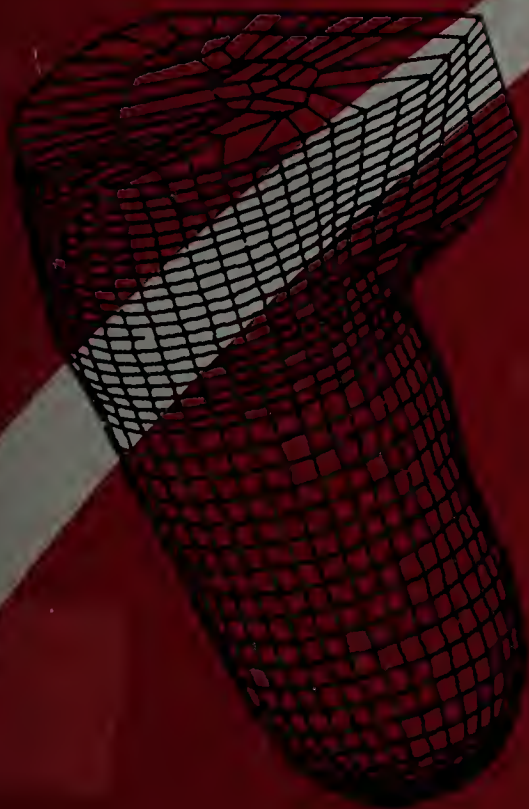




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Rehabilitation R&D Progress Reports

Research Impacts Clinical Practice



1990

Veterans Health Services and Rehabilitation Research
Rehabilitation Research and Development Service

ON THE COVER

Research and development carried out at the Northwestern University's Prosthetics Research Laboratory and Rehabilitation Engineering Center are featured on the front and back covers. On the front cover: Finite element mesh for analysis of AK socket stresses (at left); AK-BK amputee walking on forceplate with video overlay of floor reaction forces (at right). On the back cover: An EPP (extended physiological proprioception) control system for high level upper limb amputees. Progress reports related to these topics are on pages 5-7, 13, 15, 17, 20, 29-32, and 39.

Photos and art for the covers courtesy of Northwestern University's Prosthetics Research Laboratory and Rehabilitation Engineering Center. Cover design, Holly Jellison; illustration and production, Frank Vanni, VA Prosthetics Assessment and Information Center.



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Each report must include the following information:

1. Full names, titles, and addresses of the principal investigator and coauthors and location of the research activity.
2. Telephone number of the principal investigator.
3. Full name and address of the sponsoring organization(s), as well as the specific funded program. Include name of organization's director, if applicable.
4. Complete and accurate references (i.e., exact title, author(s), publication title, volume, issue number, date, and page numbers). Incomplete references will be deleted.
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Rehabilitation R&D Progress Reports 1990

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ELECTRONIC PRODUCTION

The progress reports in this publication were organized with a multiuser database. The database manager was VA Fileman, running under Micronetics Multiuser Mumps (MSM) on a Dell PC AT. The database was used to compile the reports and to produce the table of contents, sponsor index, subject index, and author index. The database was also used to cross-reference progress reports. Voluntary technical support for the database operation was provided by John Bowman.

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- 434 Prophylaxis for Deep Vein Thrombosis in Acute Spinal
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- 451 Wheelchair Evaluation
- 451 Rehabilitation Engineering Center for Personal Licensed
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- 452 Research on Improving Wheelchair Frame Durability

- 453 A Wheelchair for Exercising Paralyzed or Paretic Limbs of Paraplegics
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- 458 Electric Wheelchair Controllers: Effect of Speed and Acceleration on Driving Performance
- 458 Isometric Joystick versus Displacement Joystick for Simulated Wheelchair Control
- 459 Evaluation of the MANUS Wheelchair-Mounted Manipulator in the Home, Work, and School Environment
- 460 Adaptive Speed Control for Electric Wheelchairs
- 460 An Improved DC-DC Converter
- 460 Brushless DC Motor Evaluation
- 461 Reliable, Available, and Safe Electric Wheelchairs
- 461 Research on Wheelchair Frame Modeling
- 463 The MIT Damped Joystick: A Control Interface for Tremor-Disabled People
- 463 Development of a Smart Wheelchair
- 464 Identification of Desirable Features of a Smart Wheelchair
- 465 Further Development and Clinical Testing of a Multifunction Vehicular Interface Unit for Quadriplegic Drivers
- 466 Effects of Flexible Passive Standing in Patients with Spinal Cord Injuries

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- 468 Development and Clinical Evaluation of an Adjustable Modular Postural Seating System for Persons with Mild to Severe Physical Involvement
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- 470 Development and Evaluation of an Advanced Pressure-Mapping System for Prescription of Seating Wheelchair and Positioning Systems
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- 477 Identification and Evaluation of a Comprehensive Skin Care Program to Prevent Skin Breakdown in Spinal Cord Injured Patients
- 477 Treatment of Pressure Ulcers
- 478 Use of Direct Current Stimulation in Pressure Sore Healing
- 479 Therapeutic Intervention for Healing Pressure Sores with Electrical Stimulation on Persons with Spinal Discontinuities
- 480 An Analytical Service Demonstration of the Role of Biochemical and Behavioral Indicators in the Prevention of Recurrent Pressure Sores
- 480 Pressure Sore Prevention: An Effective Stepped Care Approach
- 481 Bedsore Biomechanics

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- 483 Periosteum as a Functional Membrane
- 483 Enhancement of Femoral Head Fracture Healing by Means of AC and DC Electrical Stimulation
- 484 Biomechanics of External Fixation of Tibial Fractures
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- 485 Morphologic and Ultrasonic Analysis of Normal and Ischemic Human Wounds
- 486 Diabetic Foot Ulcers: Quantifying the Effects of Nonsurgical Treatments
- 487 Bone-Derived Cells Produce a Chemotactic Factor

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- 488 Development of a DHCP Database and Quality Assurance Information System for Audiology and Speech Pathology: A Pilot Study
- 488 National Invitational Conference on the Development of a Health Services Research Capacity in Physical Disability and Rehabilitation
- 489 A Model for the Production of Low Demand Assistive Devices
- 489 Health Insurance Coverage of Disability Beneficiaries

I. Amputations and Limb Prostheses

For additional information on topics related to this category see the following Progress Report: [138].

A. General

[1] Mechanism-Based Treatments for Phantom Limb Pain

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Sponsor: VA Rehabilitation Research and Development Service (Project #A314-2RA)

Purpose—The purpose of this study is to determine causes and mechanisms of phantom pain and to test treatments based on identified mechanisms.

Methodology—Amputees reporting stump and/or phantom limb pain were recorded using thermographic measures of near-surface body heat and surface electromyographic measures of muscle tension. Each subject was recorded between two and four times while reporting varied pain intensities. Each subject used a body map to identify areas with phantom, no, and normal sensations. When decreased blood flow in the stump is related to increased burning phantom limb pain, peripheral vasodilators and temperature biofeedback are used to decrease the phantom pain. When increased muscle tension and spasms in the stump are related to episodes of cramping phantom pain, muscle relaxants and muscle tension biofeedback are used to control the pain.

Results—*Physiological Mechanisms.* Among amputees, a consistent inverse relationship between intensity of pain and stump temperature relative to the intact limb occurred for burning, throbbing, and tingling descriptions of phantom limb pain and stump pain, but not for other descriptions. Surface electromyographic (EMG) recordings made while amputees are experiencing multiple, brief, discrete episodes of cramping phantom pain show a clear predictive relationship between the start of spasms in the residual limb and the onset of phantom pain. There is no convincing evidence that major

personality disorders are important in the etiology of chronic phantom pain. Evaluation of logs indicates that phantom limb pain can be affected by the external environment.

Treatment. The treatments described above have been completed for most of the subjects, but follow-ups are not complete. Pending confirmation upon follow-up, it is clear that burning phantom pain responds to interventions which increase blood flow to the residual limb while cramping phantom pain responds to interventions which decrease tension and spasms in major muscles to the residual limb. Shocking/shooting phantom pain does not respond well or consistently to either type of intervention.

Future Plans—Limited local Army funds, as available, will be used to perform pilot studies which will record physiological factors and phantom pain in subjects' normal environments to establish predictive relationships between variables.

Recent Publications Resulting from This Research

Phantom Limb and Stump Pain. Sherman R, in *Neurologic Clinics of North America* 7(2):249-264, R. Portenoy (Ed.). Philadelphia: W.B. Saunders Co., 1989.

Treatment of Post-Amputation and Phantom Limb Pain. Sherman R, Barja R, in *Current Therapy of Pain*. K. Foley, R. Payne (Eds.). Toronto: B.C. Decker, Inc., 1989.

Mechanisms of Phantom Pain: New Findings. Sherman R, in *Proceedings of the 21st Annual Meeting of the Association for Applied Psychophysiology*, Washington, DC, 1990.

The Mystery of Phantom Pain: Growing Evidence of Physiological Mechanisms. Sherman R, Arena J, Ernst J, Biofeedback Self Regul (in press).

The Relationship Between Situational Stress and Phantom Limb Pain: Cross-Logged Correlational Data from Six Month Pain Logs. Arena J et al., Psychosom Res (in press).

[2] Feasibility of Green/Red/IR PPG in Assessing Ischemic Tissue Survival: A Pilot Study

Bok Y. Lee, MD; Lee E. Ostrander, PhD

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Sponsor: VA Rehabilitation Research and Development Service (Project #A89-25PA)

Purpose—The purpose of this study is to examine optical skin reflectance at multiple light wavelengths in the presence of soft tissue ischemia. The study seeks to identify clinically useful parameters and a measurement protocol for comparing reflectance methods with fluorometry. The application is the assessment of soft tissue ischemia, which is encountered with pressure ulcers, tissue necrosis associated with vascular disease, and trauma. The ischemia, when unrecognized, can lead to further unexpected death of soft tissue following intervention to close open wounds.

Methodology—Fluorometry and a variety of other methods are available for perfusion measurements. However, there is a need to consider methods which

might provide totally noninvasive and easy to use measurements. Recently reported studies by us on the optical properties of soft tissue have prompted us to investigate ways in which skin reflectance spectrophotometry might provide useful data for evaluating ischemia and flow obstructions. The spectrophotometric methods are an expansion upon principles employed in photoplethysmography and pulse oximetry.

Progress—Preliminary data has been obtained from both animal studies in a surgical flap model and from post-surgical studies. The data is being correlated with tissue survival outcomes and examined in the context of soft tissue perfusion models.

[3] Intraoperative Assessment of Amputation and Decubitus Flap Perfusion

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Sponsor: VA Rehabilitation Research and Development Service (Project #A463-RA)

Purpose—The surgical flap is a widely used and often effective closure following removal of necrotic and gangrenous tissue from a limb. This form of treatment permits salvage of limbs and tissues, thereby preserving more patient function and reducing requirements of extended rehabilitation. However, flaps to cover an amputation site in the presence of peripheral vascular disease are reported to show a failure rate of 20%. In the spinal cord injured patient, flaps to cover a pressure sore site are reported to show a 6 to 7% failure rate associated with suture separation and necrosis. Prediction of these failures before they occur would permit an alteration of surgical procedures with reduced morbidity and mortality. At the present time, the survival of the flap remains in question for extended periods after surgery.

Methodology—Our hypothesis is that quantitative measurements taken intraoperatively after the flap has been formed can be used to assess flap physiological function, and can be predictive of flap survival. We have conducted intraoperative testing to determine the presence or absence of perfusion based upon fluorescein flowmetry. Measurements were taken immediately postoperatively with tissue survival 7 days after the operation.

Since the testing is done intraoperatively after the flap is developed, and also after the flap has been moved into its anticipated location, the results should be of more use in prediction than testing done preoperatively.

Preliminary Results—In nine patients studied, two showed fluorometric readings consistent with poor perfu-

sion. One subject, an overweight smoker, showed a maldistribution of skin perfusion prior to surgery, including areas of hyperemia and ischemia in measurements at 24 sites. This data supported the conclusion that measurements at a single site can produce an inaccurate view of extremity perfusion status and that readings at multiple sites can elucidate pathologic changes and the return towards normal perfusion levels.

One subject studied had a service-connected spinal cord injury. A surgical flap was developed and utilized to repair a decubitus ulcer wound. Immediate post flap reconstruction, the fluorometry studies revealed a region of low perfusion at a flap corner. Upon further examination, there was visual evidence to suggest mechanical tension. Subsequently, the flap separated in this suspect

region. From this data, we conclude that fluorometry can predict regions requiring further attention.

These clinical results to date, although limited in number, are consistent with the view that skin perfusion must be adequate if healing is to occur. Laboratory animal data in our recent work also support this view. A surgical flap model provided a gradation of perfusion levels from near normal perfusion at the base to severe ischemia and eventual tissue necrosis at the end of the flap. A study of 132 sites for 15 flaps was done. Study results following flap formation showed fluorometry sensitivity and specificity of 100% and 97% respectively, in predicting flap survival, while initial visual appearance of the flap could not be used to predict survival.

[4] A Program for Evaluating the Dysvascular Patient

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Sponsor: VA Rehabilitation Research and Development Service (Project #A086-4RA)

Purpose—This program consisted of two studies: 1) experimental-clinical examination in arteriosclerotic occlusive disease; and, 2) the role of blood perfusion and regional tissue mechanics measurements. The premise being that noninvasive assessment of blood perfusion and mechanical properties of a limb will provide needed information for prediction of optimal intervention (surgical and/or pharmacological) to achieve healing while minimizing the length of hospital stay and costs. The measurements applied in this study for blood perfusion are inert H₂ clearance, fluorescein fluorometry, and tissue mechanics measured by pressure displacement relationships of limb tissues.

Methodology—The program was a continuation of a previous program which consisted of development of instrument systems followed by experimental and clinical studies and data analysis. The animal studies focused on the sensitivity of the instrument responses to conditions of poor perfusion, edematous changes, and postsurgical intervention. Clinical studies involved accumulation of serial testing in patients during and subsequent to treatment. For comparison, standard noninvasive vascular tests were performed.

Implications—Arteriosclerotic occlusive disease (ASOD) is a major cause of morbidity and mortality in the United States. Within the VA patient population, high incidence of ASOD in the lower extremities is reflected with the loss of function of the lower extremities, reduced mobility, increased morbidity, and interference with daily activities. Ischemic ulcers and gangrene become a chronic medical dilemma. When amputation is necessary, this leads to irreversible functional loss and lengthy rehabilitation. Given these conditions, the early assessment of limb tissue viability and the effects of different treatment modalities (i.e., surgical/pharmacological) is vital. Reduction of costs of care associated with rehabilitation requires improved noninvasive instrumentation for early assessment and treatment of ASOD.

Results/Future Plans—Significant progress has been made in both clinical and experimental studies. Instrumentation and testing techniques have been developed for the assessment of blood perfusion and mechanical properties in the limb. Both tissue compliance and fluorescein/tissue viability will be studied via individual programs.

[5] Cosmetic Covers for Upper and Lower Extremity Prostheses

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Sponsor: VA Rehabilitation Research and Development Service (Project #A252-2RA)

Purpose—This program is directed toward the development and practical application of realistic cosmetic covers for upper and lower extremity prostheses for men and women. Objectives include: 1) continuing the development and demonstration efforts begun under the previous VA contract with Franklin Research Center (FRC), toward realistic and durable cosmetic covers for hand and arm prostheses, including studies on materials and procedures for molding, casting, and intrinsic coloration; 2) conducting technology transfer and training of VA-associated prosthetists in the specialized techniques of this program; 3) conducting research and development studies toward application of the cosmetic covers to active hand systems, including FRC's conforming-grasp design; and, 4) developing cosmetic covers for lower extremity prostheses (feet and legs).

Progress—Efforts were continued on the technology of molding and casting, particularly toward eversible final molds derived from primary molds of donor hands. A promising new multistep procedure was developed: 1) a primary mold of the extremity is made with an alginate (alternatively, silicone) impression material; 2) a flexible cast is made with a flexible polyurethane (durometer 55A); 3) an eversible mold is formed from acetoxymoi-sture-curing sealants, with a very thin fluorosilicone inner layer and thicker (e.g., 2 mm) dimethylsilicone outer layer; and, 4) a multilayer addition-cure silicone cover is formed using intrinsic coloration. A silicone cover was fabricated using this technology for the passive prosthetic hand of a veteran.

A 3-day training session on the techniques and materials for making silicone cosmetic covers was held at FRC in March 1990, with certificates of completion awarded to six VA prosthetic personnel and providers. The areas covered included primary molding of the hand, casting a polyurethane master, making an eversible two-layer mold, and intrinsic coloration procedures.

Results—For the conformable grasp hand, a suitable understructure was identified. A knitted Kevlar sleeve which slides over the fingers and bunches to make a space-filling convoluted form prevents cut-through from the metal parts while not resisting joint flexion. The Kevlar sleeve is more satisfactory than liners of silicone gel or elastomeric foam.

Studies were conducted on materials suitable for covers for active hands. One promising high-tear material is a solution-based 5%-diphenyl siloxane copolymer.

Examples of several commercial prosthetic feet were obtained to investigate approaches to making realistic, durable covers. Ways of making covers with several high-tear-strength, solvent-based silicones were studied. Areas studied included mold materials, solvent removal, and silicone composites.

A flexible support was conceived for lower-extremity covers using a flexible thermoplastic foam thermoformed into the shape of the leg with convolutions incorporated to allow knee flexion with minimal resistance. Experiments showed that sheets of EVA foam (2.9 lb/ft³) can be vacuum-formed effectively over a convoluted knee-area model.

Studies were made of the stretching of skin over the ankle joint. Silicone molds were made of a human ankle region in a neutral position (with raised markers at measured points), in full dorsiflexion, and in full extension. Measurements made on epoxy casts to determine the elongation and contraction of the skin in various locations and directions will be useful in designing soft covers.

Future Plans—Efforts will continue on high-tear-strength materials and on associated molds and release agents. Covers and supports for upper and lower prostheses will be demonstrated. Training activities will be continued.

[6] Laser Doppler Evaluation of Skin Blood Flow

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Sponsor: VA Rehabilitation Research and Development Service (Project #A335-2RA)

Purpose—To predict the viability of the skin in patients coming to amputation, we have compared Laser Doppler Velocimetry Temperature Stress Test (LDV.TST), Quantitative Perfusion Fluorometry (QPF), and Ankle-Brachial Indices (ABI) in 39 preoperative patients who underwent either a transmetatarsal or below-knee amputation.

Methodology—LDV.TST involves heating the skin to three different temperatures (34, 38, and 42 degrees Centigrade), then doing a regression analysis of the rise in LDV signal as a function of applied temperature. Previously, we had found a significant difference in the regression coefficients for ischemic, dysvascular, and normovascular skin. As reference, we assessed comparable areas (dorsum, medial, and lateral below the knee, above the knee, and upper arm and forearm) from 20 nondiabetic controls with normovascular blood flow. Ten of the subjects were black and 10 were white.

QPF involves taking background readings of the skin with a dermofluorometer, injecting fluorescein (4-6 mg/kg) diluted to 20 cc with normal saline, over a 2-minute interval, following with a 10-minute, postinjection reading (subtracting the background). The area in question is referenced to a comparable area of color with normovascular blood flow (i.e., forearm, upper arm). Since many of these patients do not have a comparable area of normovascular blood flow, we have found a high degree of inaccuracy (35%). In each of the 39 patients, the mean dye fluorescence index (DFI) at the amputation site is used for comparison with the other measurements.

Results—Ankle-brachial indices were done on every patient at the end of the LDV.TST. This test was probably the least sensitive with regard to healing of the amputation site due to the diabetic's noncompressible arteries.

[7] Computerized Methods for Prosthetics and Orthotics

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This series of projects strives to apply the power of computers to the fields of prosthetics and orthotics. Applications we are examining include the modeling and processing of body structures.

Progress—Structural Modeling. Soft Tissue Modeling. An investigation into the static mechanics of muscular tissue was concluded. Results show that a Mooney material representation, combined with a Herrmann finite-element variational statement will accurately predict the mechanics of muscular soft tissue. In cases without significant areas of high deformation, linear, constant-dilatation elements were found to be sufficient. These are essentially the linear form of the Mooney/ Herrmann elements, yet result in models which are four times faster.

Additionally, modeling of problems involving incompressible solids was found to be sensitive to an accu-

rate specification of the incompressibility. Historically, standard (fully-integrated, displacement-based) finite-elements with a Poisson's ratio of 0.45 are used as an approximation for this case. Using generic models, however, we found this method leads to under-prediction of stresses by a factor of 5. Linear constant-dilatation elements do allow for the correct specification of incompressibility.

Above-Knee Socket Modeling. A finite element analysis (FEA) study of three clinical A/K socket designs (quadrilateral, NSNA, NURIC) was initiated. A 3-D finite-element model of an undeformed residual limb was developed consisting of 3,485 nodes and 2,673 elements. Limb and socket shape data were aligned to produce rectification maps which were input to the model as surface displacements. A loading of one-half body weight was distributed to the proximal hip.

The FEA pressures for the quadrilateral socket were highest at Scarpa's triangle, and in the broad ischial-gluteal region, averaging about 6.5 N/cm². For the NSNA socket, the pressures were more uniformly distributed with mid-limb pressure generally between 4.5 to 7.5 N/cm². For the NURIC socket (a total ischial-containment type), mid-limb pressure values were higher (5.0 to 12.0 N/cm²). The percent change in volume below ischial level was calculated for each socket and correlated fairly well with predicted mid-limb pressures.

An experiment was conducted to measure pressures at seven sites along the socket/limb interface for each socket. The highest pressures measured in the quadrilateral socket appear in Scarpa's bulge and in the ischial and gluteal areas. The NSNA socket also showed high pressures in the ischial and gluteal regions and somewhat higher pressure at mid-limb sites. The NURIC socket yielded peak pressures against the medial wall near the ischium and in Scarpa's compression, and showed the highest of the three mid-limb pressures. In general, the trends agreed with those predicted by the FEA, although the values measured are consistently lower than the values predicted.

Determination of Centers of Rotation. Work continues on examining methods to calculate the center of rotation between two rigid bodies. The methods examined in this study are: Least-Squares Estimator (LSE); Generalization of the Reuleaux Method (GRM); Maximum Likelihood Estimators (MLE). It has been found that for all methods, the accuracy and precision improve when the angle of rotation of the rigid body is larger, and/or when the measuring noise decreases. Additionally, the LSE and GRM have the same precision.

A two-step optimization procedure was developed to locate the femoral transverse axis (FTA) using knee kinematics. The first step is used to find the direction of the FTA relative to the femur. The second step is used to find a point on the FTA at the mid-width of the knee (femoral origin). To test the procedure, kinematic data for 18 knees was used, for which the position of the femoral origin and the orientation of the FTA had been previously determined geometrically and checked radiographically. The calculated FTA orientation was found to be in error by an average of 2.39 degrees (s.d. 3.73), and the origin was found to be in error by an average of 2.58 mm (s.d. 2.78).

Structural Processing. Software. Software which uses surface data information to automatically form a finite-element model of the structure has been written. Presently, only surface point data is used (i.e., internal bony shapes are not modeled).

Manufacturing Demonstration. A prototype B/K prosthetic socket was made using the stereolithography process. This was accomplished with the assistance of the Baxter Healthcare Corporation. Stereolithography relies on a laser-based instrument developed by 3D Systems that forms solid models by optically curing a photopolymer. The production of the socket, which took 2 days, was the first known application of this technique to the field of prosthetics.

Recent Publications Resulting from This Research

A Kinetically Determined Coordinate System for the Knee with Application to the Study of Joint Mechanics and Human Gait. Rovick JS, presented at the First World Congress on Biomechanics, La Jolla, CA, 1990.

[8] Prosthetic/Orthotic Materials

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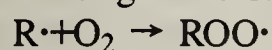
Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Standardized testing modalities are being used to characterize the composition, structure, and performance of the current armamentarium of prosthetic and orthotic polymers prior to and after fabrication, and after weathering and quenching. Also, new thermoplastic elastomeric materials are being examined for their potential for providing improved prosthetic and orthotic devices.

Progress—Properties of tensile elongation, dynamic modulus, and infrared spectra were measured on three polymers, namely, Subortholen, polypropylene, and Surlyn, having undergone four different processing treatments (i.e., "as-received," weathering, quenching, weathering and liquid nitrogen quenching).

Results—*a. Polymer degradation as proposed from monitored infrared spectra.* Weathering of the samples was performed according to ASTM standard G53-84. Specimens were placed in a weatherometer for 5 weeks in a cycle of 80 degrees C ultraviolet light for 8 hours, followed by 60 degrees C water vapor for 4 hours.

Degradation of these polymers during weathering was seen by the infrared spectra as originating in the propagation stage where:



The decomposition of the hydroperoxide ROOH into various alcohols is suggested by the observation of primary alcohol (RCH_2OH , at 1050 and 3400 cm^{-1}), secondary alcohol (R_2CHOH , at 1100 and 3400 cm^{-1}), and tertiary alcohol (R_3COH , at 1150 and 3400 cm^{-1}).

b. Tensile testing. Tensile testing was carried out on an Instron Table Model 1101 testing machine, using ASTM standard method D638-87a. Three cross-head speeds were used: 0.05, 0.2, and 0.5 in/min. Quenching was performed by heating to the manufacturer's recommended "softening temperature," followed by immediate quenching into liquid nitrogen. The liquid nitrogen temperature (-196 degrees C) is far below the glass transition temperatures of either polypropylene (-10 degrees C), or Subortholen (-80 degrees C).

The surface morphology of the Subortholen weathered tensile test specimens revealed a thin, cracked layer of embrittled material on the surface, which did affect certain mechanical properties. For Subortholen at

a cross-head speed of 0.05 in/min, a dramatic reduction of the tensile elongation, from more than 500% to about 100%, was found by weathering the as-received material. On the other hand, the liquid nitrogen quenched Subortholen increased its tensile elongation from 500% in the as-received condition to about 900%. It was interesting that if both the quenching and weathering treatments were applied to the same sample, the value of tensile elongation was three times as that of a sample which had only been weathered.

At all treatments, the specimens were negatively strain-rate sensitive (i.e., less percent elongation at higher test speeds).

c. Dynamic mechanical testing. Dynamic mechanical testing was carried out on a Rheovibron Model DDV-II-B testing machine at 11 Hz, over a temperature range from -100 degrees C to 200 degrees C. The Rheovibron applies a sinusoidal strain on the specimen and measures the amplitude of the resultant stress, and the magnitude of the phase angle δ between the stress and strain. The loss moduli definitely change as a function of temperature, and definitely decrease as a function of weathering time. The glass transition temperatures of these tested polymers appeared to remain the same during weathering.

Future Plans—Characterization activities are to be carried out on several series of thermoplastic elastomers to be compared with the conventional prosthetic and orthotic armamentarium.

[9] Information and Education Resource Unit

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The Information and Education Resource Unit assists consumers, academicians, and service providers in locating information on prosthetics/orthotics management, and the disabling conditions which need prosthetic/orthotic solutions. The Unit collects information, assembling it in a database; disseminates information via a telephone help-line; and generates new information by creating connections between existing databases and other information sources, and by sponsoring educational opportunities. New information is also generated by contacts with amputee support groups nationwide, and by creating cooperative interactions between manufacturers,

service providers, researchers, and consumers of prosthetic/orthotic services and products. The Unit does not endorse or recommend any product, service, or clinician; it often acts as a referral service to those resources which can assist the investigating party in obtaining more information about their specific area of interest.

Progress—The database currently contains over 300 entries related to prosthetics, orthotics, and disabling conditions. These entries include information on: amputation management, amputee support groups, state-of-the-art research, general disabilities, recreational resources,

self-help groups, nursing care, prosthetic/orthotic schools and service providers, prosthetic/orthotic publications, and manufacturers' information. New information on prosthetic/orthotic products and services is reviewed by the Unit, added to the database, and made available to the public. Conversion to a hypertext database solution for information management is being implemented.

The help-line, available on (312)908-6524, disseminates information in the database to the many callers contacting it monthly. Additionally, by delving into alternative resources, the help-line directs callers to other information clearinghouses or professionals which may be better able to service their request. Follow-up occurs via telephone or correspondence where the caller receives written confirmation of their request and accompanying materials if available. No charge is made for any help-line service.

Consumer feedback to the Resource Unit is formally acquired through yearly meetings of the Consumer Advisory Panel of the Rehabilitation Engineering Program. Educators and clinicians have benefitted from their invited attendance at these meetings. The Panel, consisting of persons with disabilities managed by prosthetic/orthotic solutions, met in Phoenix this year for a state-of-the-art workshop and conference in connection with the annual AAOP meeting. Input from consumers contacting the help-line is also extremely valuable, as it represents

the experience and real-life situations of prosthesis and orthosis users who do not have ready access to a body of research professionals or up-to-date information.

Programs, presentations, and publications disseminate information collected or generated by the Resource Unit. In addition to the Phoenix conference, the Unit assisted in the creation of a small part of the exhibit, "Bionics and Transplants: The World of Replacement Medicine," now at the Museum of Science and Industry, Chicago, IL. We regard papers published and presented by the staff as one method of research information dissemination. Titles of such papers are under other project descriptions in this journal. The Project Director of the Resource Unit participated in the 13th Annual RESNA Conference in Washington, DC, in June, 1990. The Resource Unit is playing a major part in organizing and hosting the Seventh World Congress of ISPO in 1992.

Brochures describing work at the Rehabilitation Engineering Program were published early this summer, and previous to this, articles about the Resource Unit appeared in two major prosthetic/orthotic journals. A Resource Unit newsletter is being planned for 1991.

Recent Publications Resulting from This Research

Northwestern University Initiates Prosthetics/Orthotics Information and Education Resource. Novotny MP, Childress DS, JACPOC 24(1):1-5, 1989.

[10] Extended Physiological Proprioception in the Control of Prosthetic and Robotic Systems for Physically Disabled Persons

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Sponsor: Natural Sciences and Engineering Research Council of Canada; Kinnear Foundation

Purpose—Extended physiological proprioception (EPP) involves controlling a prosthesis (or robotic system) by linking its position in space with the positions of intact joints of the user's body. This control method can improve accuracy, speed of operation, and safety of the controlled system.

Progress—Work has been underway for a few years on the control of prosthetic systems. Work is starting now in the use of EPP in the control of robotic systems, along with some special modifications which we are implementing. To help quantify our results and to speed up the

making of changes to our systems, we have opted for the use of 3-dimensional (3-D) simulations on a computer screen, rather than bench-top models. A 386 computer with a VGA monitor and appropriate 3-D software have been installed. Further work will be undertaken in this area during the next two years.

Recent Publications Resulting from This Research

Simulation and Modelling of a Microcomputer Controlled Above Elbow Prosthesis. Philippe-Auguste JS, Gibbons DT, O'Riain MD, Automedica 11:99-109, 1989.

B. Upper Limb

1. General

[11] Computer-Based Myoelectric Training

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Sponsor: *Hospital for Sick Children Foundation*

Purpose—Our purpose was to design, develop, and evaluate a computer-based system for training amputees to control the myoelectric signals which they will use later to operate artificial limbs.

Progress—One of the recognized limiting factors in training children to use myoelectric prostheses is their limited attention span. In 1987, the Institute proposed to investigate the possibility that computer games, with myoelectric rather than manual control, could be useful supplements to normal training protocols.

Between March 1989 and March 1990, 11 clients of the Prosthetics Research Centre used the game, and data was recorded. The youngest client was 4-and-a-half years old, and the oldest 13-and-a-half years old. These clients were segregated into three age groups, pre-school (4 to 6 years), elementary school (7 to 11 years), and early teens

(12 years and above). Several clinical observations with regard to these age groupings were made during the period of the trials.

These trials have shown that the game has definitely provided a motivating, interesting alternative to myoelectric signal training. However, whether this system has a beneficial effect with regard to client performance with a prosthesis is, at present, impossible to say.

Clinical trials are being extended to allow rigorous statistical analysis of the data to be performed. It is hoped that we can collect sufficient data to determine if any real benefit is achieved using this technique.

Recent Publications Resulting from This Research

A Computer-Aided Myoelectric Training System for Young Upper-Limb Amputees. Lovely DF, Stocker D, Scott RN, J Micro-comput Appl 13(3):245-259, 1990.

[12] Multifunctional Hand Prosthesis Based on a New Pattern of Prehension

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Sponsor: *Institut de recherche en santé et en sécurité du travail du Quebec*

Purpose—The objectives of this project are to: 1) develop a multifunctional hand prosthesis for which the prehension geometry and the architecture have been developed around the most essential opposition movements of the thumb, and within its preferred plane of flexion; 2) overcome the complexity of the design by using a three-dimensional (3-D) computer-aided program (CATIA) for both the design and modeling processes; and, 3) validate the new pattern of prehension by clinically comparing the prehension performances with a hand prosthesis featuring a traditional pincer type prehension pattern.

Progress/Methodology—Based upon the results of an ergonomic analysis of prehensile activities, a first laboratory prototype was completed in 1988. The prehension geometry was elaborated using a 3-D computer program. This has been followed by the production of a first series of six revised clinical versions which are now functionally evaluated by candidates previously fitted with an Otto-Bock myoelectric hand prosthesis.

The new hand prosthesis is constructed with a morphology resembling the natural hand and powered from a single motor. The prosthesis prehension calls upon four active fingers, each flexed at the level of the

two proximal joints. The opposing thumb is also flexed at the level of the carpometacarpal (CMP) and interphalangeal (IP) joints. It can also be rotated passively in order to perform the two complementary patterns of prehension: the tridigital and the lateral grips. The finger's metacarpophalangeal (MP) joints describe a dome curve in both the transversal and the longitudinal planes of the palm and are oriented to spread the fingers apart during extension. The fingers are made adaptive and they will flex when pushed by an external force.

Preliminary Results—The comparative prehension performance between the new hand and the Otto-Bock hand is not yet completed. However, the new prehension geometry, with the plane of flexion of the thumb (tridigital mode) intersecting the palmar plane with an angle of 45 degrees, has permitted the identification of the following functional advantages: 1) it reduces greatly the recourse to arm and trunk compensatory movements during both the approach and the utilization phases of most of the objects; 2) it allows a better orientation of many objects held for use; 3) it improves the working visibility, the cosmesis of the prehension, and the grasping stability, particularly for large objects; 4) because of the thumb trajectory in the tridigital mode, the new hand is also more suited than the pincer type for the prehension of cylindrical and spherical objects; and, 5) although it still requires to be affined, the lateral pinch has proved to be very useful in many activities.

To summarize our partial results, the new geometry seems functionally very promising. However, a certain number of design corrections would have to be implemented in the present version in order to meet the required level of reliability and all the original specifications, especially when the prosthesis is covered with a cosmetic glove.

Future Plans/Implications—Following an evaluation of the required design corrections, we are presently studying the possibility to implement them on prostheses already produced. This approach would offer the advantage of concluding the clinical evaluation more rapidly. In parallel with this study, we are also investigating the possibility of joint development, manufacturing, or commercialization of the new prosthetic hand.

Recent Publications Resulting from This Research

- Design and Evaluation of a Hand Prosthesis. Lozach Y et al., in Proceedings of the Fourth Canadian Congress of Rehabilitation, Toronto, Ontario, 138, 1989.
- Toward a Multifunctional Hand Prosthesis. Lozach Y et al., Annual Meeting, Association of Children's Prosthetic-Orthotic Clinics, Valhalla, NY, 1990.
- Design Methodology for a Multifunctional Hand Prosthesis. Vinet R, Lozach Y, Beaudry N, Drouin G, J Rehabil Res Dev (accepted for publication).

Patents

- Prothese multi-fonctionnelle de la main. Patent applied for: June 8, 1989.

[13] Myoelectric Signal Characterization in Amputees

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Sponsor: Medical Research Council of Canada

Purpose—This project is a continuation of earlier work, which indicated that myoelectric signals from muscle remnants in the residual limbs of amputees differ significantly from signals from normal muscles. The primary objective is to obtain further information on myoelectric signals from amputees. A second objective is to study the effects of various algorithms for selecting decision thresholds in level-coded myoelectric control systems. The outcome of this research will be used in optimizing future myoelectric control systems.

Progress—The analysis of amputee myoelectric signals is a cooperative project with Dr. Evelyn Morin of Queen's

University. Agreement has been reached on all aspects of data collection and analysis protocols, software has been written for use by both centers, and data collection has begun at the University of New Brunswick (data collected from 10 amputees thus far). While these data are insufficient for statistical analysis, the trend noted in the previous report seems to be persisting. That is, there may be two populations of amputees, with myoelectric spectra (from stump musculature) shifted respectively up and down in frequency relative to the normal limb, or to typical data for nonamputees.

Recent Publications Resulting from This Research

Operator Error in a Myoelectric Control Channel. Morin E, Scott RN, Parker PA, in Proceedings of the Canadian Medical and Biological Engineering Conference, Toronto, 69-70, 1989.

Spectral Characterization of the Myoelectric Signal in Infants. Morin E et al., in Proceedings of the IEEE Northeast

Conference on Engineering in Medicine and Biology, Boston, 155-156, 1989.

Criteria for Setting Switching Levels in Myoelectric Prostheses. Scott RN et al., J Assoc Child Prosthet Orthot Clin 25(1):11-14, 1990.

[14] Objective Assessment of User Interface Control Strategies for Proportionally Controlled Prostheses and Orthoses

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Sponsor: National Health Research and Development Programme, Department of Health and Welfare, Canada

Purpose—The research proposed here aims at: 1) developing a laboratory system which will facilitate the objective evaluation of an individual's performance in reaching and grasping tasks using any interface control strategy to control a wide range of assistive devices; and, 2) using this tool to compare the performance of several common interface strategies.

The research questions to be answered are: 1) Is the laboratory system a reliable tool for objectively assessing the performance of a prosthetic or orthotic device? 2) Of the commonly used interface control strategies, which are the best performers? How significant is the difference in performance between strategies? and, 3) To perform well, what features should an interface control strategy have?

Methodology—The user-device interface consists of three components: 1) the command sources and transducers; 2) the proportional control strategy; and, 3) user feedback strategy.

The choice of a user interface to a prosthetic or orthotic device involves choosing a combination of all facets of the above components. "Ease of use" is often the justification for a particular choice of interface, but objective evaluation of the interface is rarely done. The focus of this study will be the first two components of the user interface.

Progress—The system will be designed so the full range of command source transducers and prosthetic or orthotic devices can be tested with the system. At the heart of the system is a software program called the Interface Strategy Management System (ISMS). The ISMS selects the appropriate strategy modules required to implement a particular interface strategy. The ISMS uses these

modules to process the command sources and feedback from the prosthesis or orthosis. The processed information is presented as a positional command to the assistive device. In the assessment phase of the project the laboratory system will be used in the evaluation of four common user interface control strategies. Initially, the command source will be a 2-axis joystick controlled by shoulder movement. The assistive device will be a powered prosthetic arm with an electric hand and electric elbow. The subject will be asked to reach for an object, grasp it, and place it on a target. The target and object will be placed automatically in different work planes under computer control. The tests aim at evaluating the user's ability to integrate prehension/release of the prosthetic hand, flexion/extension of the prosthetic elbow and movement of the intact shoulder. The performance of each of the interface strategies will be measured according to: 1) reaction time: the time from the placement of the target and object until the subject begins to move the prosthetic limb. We hypothesize that reaction time will indicate the amount of conscious planning required to use the strategy; and, 2) total time to complete the task. We hypothesize that this time will indicate the feasibility of integrating the strategy into a functional activity.

Twenty able-bodied subjects will participate in the study. Five subjects will be randomly assigned to each of the following strategies: 1) *Velocity control*. Elbow flexion and hand opening will be proportional to vertical shoulder velocity. Elbow extension and hand closing will be proportional to horizontal shoulder velocity. The subject will use a quick jerk of the shoulder to switch from hand to elbow control. 2) *Positional control*. The vertical joystick axis will be proportional to elbow position and the horizontal axis to hand position. The prosthesis will lock if the shoulder is motionless for 1 second, and

unlock if shoulder excursion passes the locked position. This is similar to the strategy used in the Utah Artificial Arm. 3) *Impedance control*. Joint stiffness will be proportional to the sum of signals from the two joystick axes. The velocity of the joint will be defined as in velocity control. 4) *On-Off control*. The user either moves the elbow or hand at full speed or keeps them stationary. No intermediate speeds (proportionality) are allowed.

The entire assessment procedure will be repeated using an EMG command source. The vertical joystick axis will be replaced by biceps EMG and the horizontal axis will be replaced by triceps EMG.

Results—This project is currently in the development phase and no results can be reported at the present time.

[15] Improved Actuation of Body-Powered Prostheses

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Approximately 90% of all upper-limb prosthesis-wearers still wear body-powered systems. The purpose of this project is to develop improvements to these systems ranging from new designs for voluntary-closing prehensors to more efficient cable systems.

Progress—*Quantitative Evaluation of Body-Powered Prostheses*. The goal of this phase is to develop methods to measure the force and excursion used in operating prostheses which can be used to determine the operating characteristics including range of force, excursion and mechanical energy required. A buckle transducer that can easily be slipped into any harness without modification was designed and tested to measure harness force. To measure excursion, 1 mm diameter mercury-filled Silastic strain elements were used. The output from both devices was analog voltage which can be read into a digital computer.

Alternative Cable Material. An ultra-high molecular weight polyethylene, Spectra, was evaluated as an alternative to stainless steel cable for actuating prostheses. Various tests including tensile, fatigue and friction, comparing steel and Spectra indicate that the latter would be an acceptable alternative.

Custom end fittings were designed which are compatible with conventional prosthetic devices. They utilize an internal taper which captures a simple knot tied in the Spectra cable. Clinical tests of Spectra systems at 16 clinics throughout the U.S. have been completed. Spectra compared favorably with conventional methodology.

New fittings have been designed which are easier to adjust for cable length than the tapered fittings. Preliminary fatigue and tensile tests indicated that these fittings offer adequate performance; production will begin soon.

Holding Assist. Voluntary-closing prehensors offer advantages over the more prevalent voluntary-opening devices, but suffer in occasional situations from requiring active cable tension to keep them closed. A holding assist is a mechanism which can keep the gripper closed, but still allow the prehensor to function normally. A prototype device based on the concept of an overrunning roller clutch was designed and tested. It was designed to maintain grip force as long as a small tension was maintained in the cable. The transition from the locked to open states was rough and unpredictable. Therefore, it was redesigned to function in an alternating mode so that it would remain locked without the need to apply cable tension.

Redesign and testing is continuing, including the preliminary investigation of using hydraulic mechanisms to provide the desired locking.

Synergetic Prehensor. All mechanical prehensors must obey the fundamental laws of mechanics, so that there is a trade-off between cable excursion required and grip force generated. The act of gripping, however, requires minimal mechanical energy in most cases. The goal of the synergetic prehensor is a device which can develop large grip force with minimal cable force and excursion requirements. This is accomplished with two moving fingers. The *sizing finger* is designed to adjust the prehensor aperture as desired. Once an object is encountered, the *gripping finger* applies a large gripping force with a high mechanical advantage linkage. Many mechanisms for locking the sizing finger and powering the gripping finger have been explored.

Results/Implications—A prototype prehensor has been built and is currently undergoing laboratory testing and refinement.

In the course of fatigue testing of cable systems, it became apparent that the lift tab of a conventional dual-control above-elbow prosthesis was a key failure point due to the sharp bend the cable undergoes at that point. A simple *lift pulley* was designed and tested which eliminates the sharp bend. Instead, the cable always passes tangent to the pulley. The system becomes more efficient and exhibits significantly increased fatigue life for both

steel and Spectra cables. The device is being evaluated for commercial production.

Recent Publications Resulting from This Research

Holding Assist for a Voluntary-Closing Prosthetic Prehensor. Carlson LE, Heim R, ASME Dyn Syst Control Div Publ 17:79-87, 1989.
Spectron 12 Cable for Upper-Limb Prostheses. Carlson LE, Radocy B, J Prosthet Orthot (accepted for publication).

[16] Functional Biomechanical Characterization and Functional Design Specification: Upper-Extremity Prosthetics

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The title represents a set of projects within a component of the NIDRR-funded Rehabilitation Engineering Center in Prosthetics and Orthotics. The projects are part of the effort to develop methods of characterizing upper- and lower-limb prosthetic and orthotic components and devices and to gain understanding of the relationship between design characteristics and functional performance. The upper-extremity prosthetics projects are divided under two areas of investigation: 1) increasing the security of grasp with a prosthetic prehensor; and, 2) improving approach trajectories and alignment of prehension devices.

Within the first area, two lines of work are being pursued. One is to characterize the types of materials currently used to cover prehension surfaces and identify those characteristics which contribute most effectively to prevention of slip. The second line of work is the development of a slip transducer to be used in an automatic gripping system adapted for commercial electrically-powered prehensors. This report will focus on these two lines of work.

Progress/Preliminary Findings—*Characterization of prehensor surface materials.* The first effort in this area has focused on a study of the frictional properties of elastomer surface materials currently used in commercial prosthetic prehensors. The study included neoprene (used to line Hosmer Dorrance split hooks), "rubber gripping pads" (used with the Otto Bock Greifer), polyvinyl chloride (PVC) glove material (Otto Bock), and silicone glove material (Centri). The primary testing apparatus allowed for direct measurement of the normal

force applied to the sample, the frictional force, and the shear rate.

Preliminary analysis of the data indicates that the coefficient of friction (defined classically as the ratio of the frictional force to the normal force) decreases non-linearly with increasing normal force. This finding is in agreement with published data on other soft materials with elastomeric properties.

Backing materials of various hardness were studied in conjunction with PVC glove material and included aluminum (high hardness), PVC samples from an Otto Bock System Inner Hand (medium), and Aliplast (low). Data from these experiments indicate that the choice of material over which the surface material is applied (the backing material) can significantly affect the frictional property of the assembly.

Results from experiments varying the shear rate and the surface area of contact are presently being analyzed.

Slip detection for automatic gripping. Progress during the past year has concentrated on refinement of the slip transducer and implementation of the slip detection and automatic grasping system with a commercially available electric-powered prehensor. The slip transducer is based on a piezoelectric polymer polyvinylidene fluoride (PVDF). The transducer's common mode rejection (to extraneous mechanical vibrations) was significantly improved by producing two interdigitated transducers within the same polymer layer.

Realization of the system in operation with an electric prehensor required further development to eliminate sources of electrical and mechanical noise arising from attachment of the transducer to a motorized component.

This was achieved by a combination of electrical and mechanical shielding, and electronic processing of the signals coming from the composite slip transducer.

The system, in prototype form, has been demonstrated with the NUVA Synergetic Prehensor. This electric-powered prehensor (developed with funding from the Department of Veteran Affairs Rehabilitation Research and Development Service and commercially available through Hosmer Dorrance Corporation) responds immediately to a drive signal (as would be

generated by the slip detector), and develops force at a sufficient rate to stop a slip event. An earlier attempt to utilize the Otto Bock Greifer was unsuccessful because this prehensor has a time delay before the force begins to increase in response to a drive signal.

Recent Publications Resulting from This Research

Slip Detection and Automatic Grasping for an Externally Powered Prehensor. Knox E, Masters thesis, Northwestern University, Chicago, 1990.

[17] Control Strategies for Artificial Limbs

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Sponsor: *Natural Sciences and Engineering Research Council of Canada; Liberty Mutual Research Center*

Purpose—Our purpose is to develop a system for comparative evaluation of alternative control strategies for multifunction prostheses.

Progress/Methodology—Several elbow-hand control strategies are utilized by commercial myoelectric arm prostheses. More are proposed in prosthetics literature. In order to facilitate comparative evaluation and selection of the most suitable one, a computer-controlled model is being developed.

Myoelectric signals are fed into the computer via the analog-to-digital converter channels. One of several software-implemented control strategies is used to process the signals. Two digital-to-analog converter channels link the computer with a commercial elbow

mechanism and an electric hand, thus allowing for a realistic visual feedback to the subject. The arm assembly is mounted against a semicircular board on which a random sequence of target positions is displayed. Throughout the duration of the arm movement, its position information is fed back into the computer, compared with the generated target, and stored. The positioning errors are collected in file for further analysis.

Results/Future Plans—The hardware for arm control and target decoding has been prototyped. The software interface to the arm and to the subject has been developed and tested. Further work will involve the building of the hardware control block in its final form, software coding of the strategies, and testing of the system with the subjects.

[18] VLSI Telemetry Implant for Myoelectric Control

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Sponsor: *Natural Sciences and Engineering Research Council of Canada*

Purpose—The objective of this study is to design and develop a surgically implantable very large scale integrated (VLSI) telemetry system for the acquisition of site-specific myoelectric signals.

Progress/Methodology—Work has progressed in two distinct areas: differential amplifier design, and the power induction scheme. The current approach to ampli-

fier design is to investigate the use of current feedback using active current mirrors to implement a differential amplifier.

Work has continued in the power induction field to improve power coupling efficiency. The effects of body tissue attenuation have been briefly studied. However, no attempt was made to model the inhomogeneity of the arm, in particular the effects of the bone.

Future Plans—Direction for further work in this area has been identified as implementing a high-efficiency power amplifier/oscillator for driving the induction

system. To this extent, the Class E configuration looks very promising, with quoted efficiencies of the order of 90%.

B. Upper Limb

2. Above-Elbow

[19] Implementation of Extended Physiological Proprioception for Prosthesis Control

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Sponsor: VA Rehabilitation Research and Development Service (VA Contract #U55P-2069)

Purpose—Extended Physiological Proprioception (EPP) is a control concept that has demonstrated certain advantages for the position control of prostheses. The goal of this project is to develop an EPP control system for an electrically-powered arm, fit it to an above-elbow amputee and evaluate its performance.

Progress—A new design for the transducer has been designed for a Boston Arm. Located on the lateral side of the elbow, the transducer fits within a 1 cm thick by 5 cm diameter housing. A small control cable passes through a miniature Bowden housing to transmit the control force to the transducer. A force-sensitive resistor (FSR) inside the housing senses cable tension and converts it to a DC electrical signal. Application of tension

to the control cable causes the elbow to flex, while relaxation of tension drives the elbow in extension.

Results—Laboratory testing has been completed with the new transducer. This included random tracking and blind positioning, in which the subject flexes the elbow repeatedly to a predetermined location without visual cues. Results for the Boston Arm with EPP were comparable to the amputee's body-powered prosthesis and to his normal limb.

Future Plans—The system will be sent to Liberty Mutual Insurance in Boston, who generously loaned us the Boston Arm, for evaluation as an addition to their commercial product line.

[20] Improvement of Body-Powered Upper-Extremity Prosthetic Components: A Modular Electromechanical Lock Actuator—A Positive-Locking Shoulder

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Sponsor: VA Rehabilitation Research and Development Service (Project #A306-2DA)

Purpose—Based on experiences with prostheses for persons with high-level amputations, this laboratory believes that body-powered or manually-positioned positive-locking components, with their comparative mechanical simplicity, general ruggedness, and lower cost, have not been fully exploited. Mechanical arm prostheses can be configured for above-elbow and

shoulder disarticulation fittings in which the body-actuated elbow/prehensor control cable can also be used to position positive-locking wrist components (for rotation and flexion). This configuration has many advantages. Perhaps most significant among these is that the cable control utilizes the person's otherwise intact musculoskeletal and sensory systems. Consequently,

there is close coupling between the user and the prosthesis, presumably reducing the mental effort required in positioning the prosthesis. Once positioned, the joints are locked in place through some mechanical control.

We believe that the dependency on mechanical linkages to operate the locking mechanisms in these devices limits their effectiveness for the user and complicates the prosthetic fitting. To provide more efficient and versatile control of these components, a simple, modular electromechanical lock actuator is being developed which can be used in conjunction with existing cable-operated elbows and positive-locking wrist components. The principal advantage of the lock actuator is the replacement of the high forces needed to operate the mechanical controls used now with the considerably lower forces needed to operate an electrical switch controlling a motorized actuator. A second advantage is greater facility in placement and configuration of the switch control over that possible with a cable or lever mechanically linked to the locking pin.

Progress/Preliminary Results—Modular electromechanical lock actuator. A trial fitting of a prototype electromechanical actuator adapted to the locking mechanism of a USMC cable-actuated elbow has been carried out in conjunction with the Orthotic/Prosthetic Clinical Service Department of the Rehabilitation Institute of Chicago. The elbow was part of a preparatory body-powered shoulder disarticulation prosthesis used by a person with quadrimembral amputations over a period of 3 1/2 months. The controller for the lock was operated by a momentary push switch mounted to the socket and actuated by the chin. Switch closure occurred with approximately 4.5 N (1.0 lb-force). The mechanical chin-operated lock actuator generally used (the Sierra Nudge Control) would require approximately 36 N (8 lb-force) to cycle the lock.

Reliability problems with the electronic controller and with the actuator itself have been corrected by rela-

tively minor design changes, and further field testing is planned.

As a spin-off of this project, we have adapted the electronic controller for use in sequential control of a switch-actuated Boston Elbow and switch-actuated electric prehensor. The arrangement enables one control action to operate either the elbow or the prehensor and a second (generally less capable) control action to cycle the control. The Orthotic/Prosthetic Clinical Service Department has fitted two prosthetic systems using this control arrangement.

Positive-locking shoulder. Toward the design of a locking shoulder joint appropriate to a shoulder disarticulation amputation, we are using a prototype computer-based prosthesis design system to investigate the hypothetical result of locking the shoulder at various flexion angles. The primary effects we are studying are changes in the work envelope in which the prehensor of the prosthesis can be positioned, and changes in the body contact map (the area on the body which can be touched with the prehensor). Our purpose is to determine if a shoulder joint having a small number of locking positions (possibly only two or three), could provide adequate functional advantage in comparison to a joint with a greater number of discrete positions or a joint having infinite locking positions. A joint having a small number of locking positions may be simpler mechanically, which in turn may permit a smaller, lighter design.

Recent Publications Resulting from This Research

Positive-Locking Components and Single-Cable Control of Prehensor Positioning in Cable-Operated Arm Prostheses for Children (Abstract). Heckathorne CW et al., *J Assoc Child Prosthet Orthot Clin* 24(2-3):38, 1989.

Four-Function Hybrid Arm Prosthesis Incorporating an Electric Wrist Rotator and Prototype Electric Prehensor. Uellendahl J et al., in *Proceedings of the 13th Annual RESNA Conference*, Washington, DC, 167-168, 1990.

Physiological Control and Body-Powered, Multi-Joint, Locking Arm Prostheses (Abstract). Heckathorne CW et al., *Am Orthot Prosthet Assoc Almanac* 39(1):117, 1990.

[21] Development of Advanced Body-Powered Prosthetic Arms

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Sponsor: VA Rehabilitation Research and Development Service (Project #A421-DA)

Purpose—The primary objective of this work is to design an advanced, body-powered artificial arm. The design criteria include: an adjustable elbow cable excursion to

simplify fitting; a cable recovery system which allows independent elbow and terminal device control each with full cable actuation; a lightweight and strong structure

with a front hinge for high excursion capabilities; and, internal cabling using polymer cable materials for better cosmetics.

Methodology/Progress—Packaged in the humeral section of the arm is the actuation mechanism which consists of the state changer and elbow lock. The state changer sequentially changes the control of the actuation cable from the elbow to the terminal device when the elbow unlock/lock is changed. A prototype of the actuation mechanism has been built and has undergone evaluation. Modifications and redesign are currently being done to improve the manufacturability of the arm, and the adjustability of the arm to the amputee. The terminal device cable routing is such that it can be run inside the forearm to attach to a center pull hand or be run outside the forearm to attach to a standard hook-type terminal device.

The design of the structure involves the material selection and manufacturing techniques. We have focused on injection molding and resin transfer molding (RTM). Injection molding is estimated to be half the cost of RTM, but also less strong. We have designed and injection-molded a forearm structure. Strength tests will be performed to see if the structure meets our criteria. If it

is determined that the injection-molded structure cannot meet the criteria, we will then pursue resin transfer molding. The forearm is a one-piece structure for strength and good cosmetics. The distal end of the forearm is constant diameter so it can be cut to the desired length for the amputee and still enable the wrist unit to be easily attached. The forearm length is adjustable from 5 inches to 12 inches.

Preliminary Results—We have investigated polyethylene (Spectra 1000) fiber cables for use as the control cables for the arm and terminal device. Of interest is the wear and fatigue of the cables when run around pulleys, through cable housings, and rubbing on dry surfaces. We have completed the wear tests.

One of the main difficulties with the use of polyethylene cables is the problem of attachment to terminations. Simple knots do not hold, and glue will not bond to polyethylene, so it is difficult to make a simple, small, neat termination. We have designed a termination system which can attach the cables to standard prosthetic devices. The cables and termination systems are undergoing tests on amputees. The steel cables of their prostheses are replaced without cable systems.

[22] Extended Physiological Proprioception (EPP): An Electronic Cable-Actuated Position-Servo Controller for Upper-Limb Powered Prostheses

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—Experience has shown that users of electric-powered multi-joint prostheses using “velocity-control” operation, such as with switch or myoelectric controllers, give considerable attention to the control of the prosthetic components, primarily through visual monitoring of the component’s response to the controlling action. Such systems having two or more powered components are generally arranged with the components operated sequentially so that the user need attend to only one component at a time. Efforts to provide coordinated control through multiple velocity-control sites have been, for the most part, clinically unsuccessful.

On the other hand, users of body-powered cable-actuated components generally appear to have better positioning control of their components and, in hybrid arrangements, are able to operate the body-powered com-

ponents in a coordinated manner with velocity-controlled electric-powered components. The linkage of the body movement to the prosthetic component through the harness and control cable gives the user direct control over the position, velocity, and acceleration of the component and perception of that movement through the proprioception of the controlling physiological joints. D.C. Simpson (Edinburgh, Scotland) demonstrated empirically that linking body movements to externally-powered (pneumatic) components in a position-servo arrangement enabled children to control four degrees-of-freedom simultaneously in such coordinated activities as feeding. We have demonstrated quantitatively, through two-degree-of-freedom pursuit tracking experiments, the superior performance of cable-linked force-actuated position-servo control over velocity control.

Our recent goal has been the design and implementation of cable-actuated position controllers to improve the control of multi-joint electric-powered prostheses.

Progress—We have made progress in two areas. First, we have begun implementing electronic cable-actuated position controllers, or extended physiological proprioception (EPP) controllers, in clinical fittings. Our first fitting, in conjunction with the Orthotic/Prosthetic Clinical Service of the Rehabilitation Institute of Chicago, was of a person with a unilateral above-elbow amputation. The residual limb was too short to provide adequate excursion and force for operation of a body-powered elbow in conjunction with a myoelectrically-controlled hand-like prehensor. The body-powered elbow was replaced with a NYU-Hosmer electric elbow operated by one of our controllers.

With this controller, the electric elbow is actuated in the same way that the body-powered elbow would have been actuated (i.e., a cable and control strap attached between the prosthetic forearm and the suspension harness is pulled by glenohumeral flexion). However, the power to flex the elbow and lift the forearm is not provided by the body movement, but is provided by the elbow's battery pack. The body movement is used only to direct the movement of the elbow with the cable linkage, insuring that the body's joints and the prosthetic elbow move in concert during flexion, producing a one-to-one correspondence between the position of the shoulder joint and the position of the prosthetic elbow. Thus, the proprioception of the shoulder joint can inform the user of the action of the prosthesis. This prosthesis has been in use since mid-April 1990. We are presently

involved in two preparatory shoulder disarticulation fittings incorporating the electronic EPP controller for the elbow.

The drive signal for the electric elbow is derived from tension in the control cable. The force transducer now used is based on a force-sensitive resistor (FSR). Our second area of progress has been in the development of an alternative transducer based on strain gauges. The relatively high power consumption of a strain-gauge bridge has been overcome with the development of a micropower sampling circuit which pulses the bridge. The sampling circuit and bridge together have an operating current of less than 50 μ A. In comparison to the FSR-based transducer, the strain gauge transducer has a linear response to loading and considerably less day-to-day variance in output signal for a given load. A comparative study of user performance with the two types of transducers is planned.

Recent Publications Resulting from This Research

- Control Philosophies for Limb Prostheses. Childress DS, in Proceedings of the 25th Anniversary Seminar of the Strathclyde Bioengineering Unit, Glasgow, 210-215, 1989.
- Manipulation in Unstructured Environments: Extended Physiological Proprioception, Position Control, and Arm Prostheses. Heckathorne CW, in Proceedings of the International Conference on Rehabilitation Robotics, 25-40, 1990.
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[23] Quantification of Tool Use by Amputees

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Sponsor: *National Institute on Disability and Rehabilitation Research; National Science Foundation; National Institutes of Health; Whitaker Foundation; Fairchild Foundation*

Purpose—The goal of this project is to quantify the motor performance of upper-extremity amputees and identify those features of an amputation prosthesis which enable effective functional behavior such as the use of hand tools.

Methodology—A computer-controlled prosthesis emulator has been developed. This externally-powered prosthesis can be worn by an above-elbow amputee and operated through any of the usual command channels (e.g., switch control, myoelectric activity, cable pull, etc.). It can be

programmed to mimic the behavior of any prosthesis—whether an existing device or a proposed new design. It is fully instrumented to provide automatic measurements of all relevant variables (e.g., motions, forces, etc.).

Observations of intact and amputee subjects performing functional tasks (including tool use) showed that the upper extremity must frequently operate in the presence of a kinematic constraint—simple examples are opening a drawer, or sliding the hand along a tabletop. In general, these tasks cannot be performed without coordinated action of both the natural and artificial segments; therefore the ability to coordinate natural and artificial limb segments is of paramount importance. To assess this ability quantitatively, a simple but surprisingly informative test was devised: turning a crank in a vertical plane.

Progress—To provide a clinically meaningful interpretation of our crank-turning task, we performed a series of experiments to measure amputee subjects' performance on a selection of tasks representing activities of daily living (ADL), and compared the results with their performance on the crank-turning task. The ADL tasks were selected from a battery of common test tasks and were as follows: 1) donning socks (a self-care activity); 2) simulated eating (cutting play-dough with ordinary eating utensils); and, 3) rolling play-dough with an ordinary kitchen rolling pin.

One of the most important aspects of powered prostheses is the way in which the devices are controlled. We believe that to achieve satisfactory coordination of natural and artificial limb segments, it is necessary that the artificial limb respond to the amputee's muscles in much the same way that the natural limb does. A controller which mimics the natural limb's adaptable compliant behavior (technically: its *mechanical impedance*) has been developed.

To test the effectiveness of a "natural controller," measurements were made of the performance of unilateral amputees using the prosthesis emulator, programmed to respond to the amputee in two different ways: 1) the emulator was programmed to mimic the behavior of the NYU elbow. Myoelectric signals from elbow flexor and extensor muscles were used to command the speed of movement of the elbow; and, 2) using the same myoelectric signals, the emulator was programmed to mimic the compliant behavior of the natural elbow. In particular, when the amputee co-activated the elbow flexors and extensors simultaneously, the elbow stiffened (as does the natural arm).

In the past year, we have worked to develop prior work on myoelectric signal processing into a usable product. The major hurdles we have overcome are related to the calibra-

tion of the processor. Accurate calibration is essential if a reliable estimate of muscle action is to be obtained. It is especially important to properly account for the possible co-contraction of antagonist muscle groups and the modulation of muscle force by muscle length (or joint angle). Our earlier work showed that *a net joint torque in the wrong direction* will be predicted from measured myoelectric activity, if antagonist activity and the compliant behavior of muscle is not accounted for. We believe that this has had a profound impact on the effectiveness of myoelectric activity (EMG), both as a clinical measurement and as a control signal for externally-powered prostheses.

Recent Publications Resulting from This Research

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[24] Elbow Disarticulation Prosthesis

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Sponsor: *War Amputees of Canada; E.N. Biden*

Purpose—Elbow disarticulation amputees are difficult to fit because their stumps are the same length as their sound upper arm, making it difficult to attach a prosthetic elbow at the level of the normal joint. Thus, our aim is to develop and evaluate a prosthetic elbow for elbow disarticulation amputees which will allow for a naturally proportioned, functional, and cost-effective artificial arm.

Progress—Our system uses a multilink mechanism to overcome this problem. A prototype elbow has been built, fitted to a subject, and undergone a brief home trial. The elbow was fitted with support from the War Amps CHAMPS program. Funding is being sought to further this work.

B. Upper Limb

3. Below-Elbow

[25] Powered Prosthetic Fingers

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A306-2DA)*

Purpose—The primary purpose of this project is to develop externally powered fingers (including thumb) that can be combined to create a functional, yet cosmetic, partial-hand prosthesis that will preserve the independent motion of the wrist. The secondary function is to see if powered fingers (or thumb) can be used with persons who have fingers remaining, and also to examine whether they can be of use in devices for wrist and below-elbow amputations. The fingers are to be the same size as those of an average adult. They are to have one articulation (metacarpophalangeal joint).

Progress/Methodology—As this project has evolved, the emphasis has shifted from the concept of each finger as an individual unit into the idea of a total partial-hand prosthesis. A design has been finalized and a prototype partial-hand device has been fabricated.

The feasibility of individually powered prosthetic fingers arose from the advent of motors only 10 mm in diameter that are small enough to be placed within a prosthetic finger. Initial tests revealed that the motor was capable of meeting either the speed or the force criterion,

but was incapable of meeting both simultaneously. The principle of synergy was adopted to boost overall performance. In a synergetic system there are at least two motors, one delivering high speed at low force, and the other providing high force at low speed.

The resulting design uses three motors, all 10 mm in diameter with 256:1 gearheads, one each in the thumb, index finger, and middle finger. In order to achieve the maximum pinch force, the thumb motor provides the speed, and the index and middle fingers provide the force.

The drive system for the fingers uses the gearmotor mentioned previously along with a drive screw. The pinch force per finger is 8.5 lb_f using a standard number 3-56 screw thread which gives the hand a total gripping force of 17 lb_f.

The drive system for the thumb uses the same gearmotor in combination with a 3:1 bevel gear set attached to a reverse locking mechanism. This provides an angular velocity for the thumb in excess of 2 radians per second and an excursion of 3 inches at the tip.

The thumb pivot is inclined at an angle of 45 degrees to the palmar surface. This maintains a cosmetic

geometry for the thumb motion while providing a usable width of opening for the hand. The dynamic cosmesis and width of opening considerations for an inclined thumb are dictated by the synergetic design. This requires the thumb to provide all the width of opening while maintaining a dynamically cosmetic geometry.

The power source for the hand is a 9-volt transistor battery; the preferred suspension of the hand is a suction socket. Myoelectric or switch control can be used.

A redesign of the system is under way; a brief laboratory evaluation of the first prototype suggested several changes to improve performance and reduce size.

Results/Future Plans—The first prototype system that has been built exceeds the dynamic performance requirements of the original specification. However, its size and weight preclude clinical applications. A redesign of some of the components is underway to produce a smaller, lighter, more efficient version of this prototype for clinical evaluation.

[26] A Myoelectrically-Controlled, Pneumatically-Powered Hand Prosthesis for Children

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Sponsor: *Delft University of Technology*

Purpose—The objective of this project is to develop a myoelectrically-controlled, externally-powered hand prosthesis for children age 2 to 6. This prosthesis should be light in weight, fast, reliable and small enough to fit even children with a long forearm stump. Thus, the disadvantages of the presently available child-size myoelectrically-controlled, electrically-powered prostheses are eliminated.

Methodology—Theoretically, in externally-powered prostheses, pneumatic power is the better choice in terms of weight, speed, and reliability. To reduce gas consumption, the operating cycle of the hand was split into two parts: a prehension phase, and a pinching phase. In the prehension phase, the hand can be opened and closed. As soon as the thumb touches an object, the mechanism is automatically switched to the pinching phase. In the pinching phase, a force is exerted between fingers and thumb. To resist the reaction forces, a locking mechanism is provided.

Progress—A pneumatically-powered hand prosthesis was designed, built, and tested. It validated the concept of pneumatic power. A pneumatically-powered hand prosthesis can weigh as little as 100 grams, including the energy storage unit. Gas consumption is low; only 12 mg gas per cycle. The speed of operation is approximately 1 second per cycle.

Future Plans—A prototype for clinical evaluation is under construction. In order to obtain clinical results as soon as possible, several commercially available components are incorporated into the design, even though they are relatively heavy and bulky. Eventually, they will be replaced by components of our own design.

Recent Publications Resulting from This Research

Electric Versus Pneumatic Power in Hand Prostheses for Children. Plettenburg PH, *J Med Eng Tech* 13(1/2):124-128, 1989.

[27] Below-Elbow Prosthetic System

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Sponsor: *Nederlands Comité Kinderpostzegels; Innovatief Onderzoeksprogramma-Hulpmiddelen Gehandicapten; Stichting Nederlands Revalidatiefonds; Stichting Bingo Nederland; Lion's Club, Utrecht*

Purpose—The object of this project is to develop a body-powered hand prosthesis for children with a unilateral

below-elbow defect. This prosthesis should combine appearance and comfort with ease of operation.

Methodology—In order to avoid the disadvantages of both the body-powered, harness-controlled, hand prostheses (i.e., harness, low-pinching force), and the myoelectric hand (i.e., weight, speed, reliability, outward appearance), elbow control was adopted: extension of the elbow opens the hand against a spring; flexing the elbow permits the spring to close the hand. As the triceps power is only one-third of that of the shoulder muscles, a special hand mechanism will be needed to combine elbow control and a high-pinching force. In this mechanism, the operating cycle is split into two parts: the prehension phase, and the pinching phase. In the prehension phase, the hand can be opened and closed. As soon as the thumb touches an object the mechanism is automatically switched to the pinching phase. In the pinching phase, a force is exerted between fingers and thumb. A locking mechanism is provided to resist the reaction forces.

Progress—Several technical prototypes and clinical trials have resulted in an elbow-controlled hand prosthesis. It is available in two sizes: 1) type 08-10 for 2- to 6-year-olds, with system weight of 110 g, pinching force 16-20 N, and energy demand per cycle of 0.25 Nm; and, 2) type 08-32 for 5- to 12-year-olds with system weight of 150 g, pinching force 20-25 N, and energy demand per cycle of 0.55 Nm. Presently, four children are using the 08-10: one child is using the 08-32.

Future Plans—A redesign of the 08-10 is intended to reduce system complexity and weight. Also, we would like to increase the number of children using the elbow-controlled hand prosthesis.

Recent Publications Resulting from This Research

Body Powered Hand Prosthesis with Low Operating Power for Children. Kruit J, Cool JC, J Med Eng Tech 13(1/2):129-133, 1989.

[28] Evaluation of Arm Prostheses for Children with Forearm Defect by Observations in Daily Life

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Sponsor: *Nederlands Comite Kinderpostzegels; Nationaal Revalidatiefonds; Stichting Phoenix; IOP-HG; Lion's Club, Utrecht*

Purpose—In support of the activities of the Design Group for Prostheses and Orthoses of the Delft University of Technology, a field study is being conducted. The goals are to: 1) gain insight into the function of a prosthesis for a child and his parents; 2) identify the benefits and burdens of available prosthesis types; 3) formulate design specifications; and, 4) conduct comparative studies with newly-designed prototypes.

Methodology—A child with a forearm defect is observed during a normal school day. All activities executed during that day and the way they are performed, with or without the prosthesis, are registered according to a predefined classification system. Some simple measurements are executed, and a number of items are discussed with the parents and child. The participating children come from two cooperating rehabilitation centers in The Netherlands. Both centers have a specialized team for the treatment of persons with missing or paralyzed upper extremities—De Hoogstraat at Utrecht, and the Sint Maartenskliniek at Nijmegen.

Progress—Approximately 40 visits have been paid to 24 children. The prosthesis types observed were myoelectric hands, body-powered hands and hooks, and cosmetic hands. On the average, about 100 different, or differently executed actions were observed during a day, which have been compiled in a database. Prostheses with a prehension function were used in about 17 actions. The investigation included a number of newly-designed experimental prototypes. In a number of cases, it was possible to compare two different types of prostheses worn by the same child.

Results—Two prehension control principles for body-powered prostheses were compared (shoulder control versus elbow control), as well as voluntary opening versus voluntary closing of the prosthesis. The idea of elbow control was based on the wish to omit the shoulder harness. A voluntary closing device was chosen because it seemed a more natural operating principle.

The main results for the case of elbow control were that the prehension function was used less than in the case of shoulder control. This can be explained by the

smaller workspace for the prehension function with the elbow-controlled hand. However, the children preferred the elbow-controlled hand because of its comfort and its cosmetic properties.

A comparison between the voluntary opening and the voluntary closing prosthesis showed no significant differences in the use of the prehension function. Some children preferred one type, some the other. However, some improvement in the present prototype might influence this choice.

Future Plans—The project is in its final stage. Present activities are focused on publication of the results.

Recent Publications Resulting from This Research

On the Use of Prostheses by Children with Unilateral Congenital Forearm Defect. Van Lunteren A, Van Lunteren-Gerritsen GHM, *J Rehabil Sci* 2(1):10-12, 1989.

[29] Development of a Child-Size Powered Wrist

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Sponsor: *Variety Club of Ontario, Tent 28*

Purpose—Our purpose was to develop a child-size powered wrist unit to: 1) fit Variety Ability Systems (VASI) wrist lamination rings; 2) be compatible with VASI hand-body mounting arrangements; and, 3) allow the current wire harness to be routed through the mechanism to minimize the overall length.

Progress/Methodology—One prototype wrist unit has been created. The overall diameter of the wrist unit is sized to allow it to be fastened coaxially inside the current lamination rings using three equally-spaced screws. The overall length is 2 1/16 inches, making it less than 1 inch longer than our present large wrist unit.

The prototype utilizes the same motor and some of the gearing currently used on the VASI 0-3 hand. Two

additional planetary gear sets are added to achieve the required output speed. To conserve space, no anti-rollback mechanisms are used. It is expected that the friction in the system due to the high ratio of the gear train will offer the required locking.

The output shaft is coaxial with the two planetary stages and is supported by two ball bearings. The end of the output shaft is configured to fit all current VASI hand-bodies, and a mechanical stop is incorporated to limit the rotation of the wrist to 90. The wire harness enters the wrist unit at the center of the hand-body, and exits at the distal side of the motor housing. Engineering tests and clinical trials will be conducted to investigate the performance of the prototype.

C. Lower Limb

1. General

[30] Development of a Model for Modified Transfusion Enhancement of Grafts: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A980-PA); Prosthetic Research Study; Pacific Northwest Research Foundation*

Purpose—This project is part of an overall goal to develop a comprehensive research program on tissue and limb allograft transplantation. This pilot project was initiated to develop and adapt the dog model for assessing the ability of modified blood transfusions to induce immunologic unresponsiveness to subsequent transplantation of bone marrow from the donor of the blood product. This marrow transplantation model had previously been demonstrated to be a very sensitive model for detection of sensitization/tolerance induction. The rationale for these studies is that pretransplant transfusions in humans and rodents facilitate/enhance kidney transplants. In experimental models, modification of the white cells contained in the transfusion product appears to preferentially induce tolerance rather than sensitization when used for transfusion. Thus, we proposed to use the canine bone marrow transplant model to examine the effects of modified blood product transfusions on induction of tolerance in this preclinical model. Our initial hypothesis was that blood transfusion products modified to eliminate Class II lymphocyte stimulating determinants on the leukocytes contained in the transfusion product would result in lack of sensitization and possibly the induction of tolerance in this model.

Progress—We have established collaboration with the division of canine shared resources at the Fred Hutchinson Cancer Research Center and have initiated and completed preliminary experiments in this transplant model which demonstrate that modification of blood products alters their ability to sensitize/tolerize to foreign graft antigens.

Methodology—Transfusions of 50 ml of whole blood, or the platelet and leukocyte contents of such whole blood, are given on day-24, -17, and -10. On day 0, bone marrow

is transplanted from the donor of the blood product into the recipient dog. The recipient animal is conditioned on day 0 for receiving the bone marrow transplant by 920 cGy gamma irradiation from a cobalt source. Animals are maintained in intensive care for approximately 5 to 7 days after transplant, and provided leukocyte support therapy and antibiotics. The engraftment is monitored by white blood cell and platelet counts and occurs in successful engraftment by days 10 to 14. After achievement of stable engraftment, the animals are either euthanized or transferred to other studies. Engraftment is also documented by bone marrow biopsy and autopsy when appropriate. Blood products are being modified by UV-B irradiation, and heat treatment at 45 degrees C for 45 minutes, gamma irradiation, or a combination of these.

Results/Implications—In the major transplant antigen-compatible (DLA-identical) recipient donor combination, the model tests for sensitization and subsequent bone marrow rejection across minor transplantation antigens. We have found that the modified blood transfusion products almost completely prevent rejection. Historical data show that three transfusions from the bone marrow bone donor to the recipient in this model will sensitize and result in 27 out of 27 rejections. Four out of four dogs given three transfusions of UV-B irradiated platelet preparations successfully engrafted. Eight of ten dogs given three transfusions of whole blood which had been heated to 45 degrees C for 45 minutes followed by low dose (2,000 cGy) gamma irradiation also successfully engrafted. Unexpectedly, a control group of 10 dogs given three whole blood transfusions treated only with gamma irradiation resulted in nine engraftments out of 10 animals entered. This finding has not previously been reported in the literature. It suggests that low dose gamma

radiation interferes with processing and presentation of minor histocompatibility antigens on the transfusion product. The implications of this finding are that blood products might be low dose gamma radiated for use in humans in order to prevent sensitization to minor histocompatibility antigens which results in rejection of donor bone marrow, solid organs, and possibly composite tissue allografts.

Future Plans—The pilot project is completed and now this model has been incorporated into research project

#A618-RA entitled, "Prevention of Immunologic Rejection of Tissue and Limb Allografts."

Recent Publications Resulting from This Research

Treatment of Marrow Donor Blood Products with Gamma-Irradiation Prevents Transfusion-Induced Sensitization to DLA Identical Marrow Grafts. Storb R et al., in Transplantation Proceedings (in press).

[31] Development of a Limb Allograft Model for Graft Enhancement Studies: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A981-PA); Prosthetics Research Study; Pacific Northwest Research Foundation

Purpose—As part of the development of a comprehensive program in tissue and limb allograft research, this pilot study was initiated to develop the rat hindlimb allograft model. This model is to be used to study the effects of immune manipulation on graft outcome, and eventually in the future to study the effects of cloned growth factors on nerve growth regeneration/reinnervation. The practical goals of this pilot project were to establish a rat colony consisting of Lewis (LEW, RT-1^l), LEW × Brown Norway F₁ (LBN, RT-1^{l+tn}) and ACI (RT-1^a). In addition to setting up the rat colony, we proposed to establish the necessary surgical techniques to perform the whole limb transplants. This model was to be established to be initially used to study the effect of new immunosuppressants and modified blood transfusions on the induction of tolerance to composite tissue allografts in the rat.

Progress—We have established the necessary rat colony and a microsurgical laboratory. Dr. Kuroki, a fully trained microvascular surgeon, has established these microsurgical techniques and has additionally developed a technique of skin allografting. In addition, he has refined the mixed lymphocyte culture assay utilizing rat lymph node cells in order to monitor *in vitro* the immunologic outcome of the immunologic manipulations *in vivo*.

Methodology—Limb allografts are constructed using standard surgical techniques described by Hewitt, et al.

Both donor and recipient limbs are amputated at mid-femur under general anesthetic. The donor femur is then joined to the recipient site with 4-0 stainless steel suture by placement through both femurs at perpendicular angles. Stay sutures are placed through a few dorsal and lateral muscle groups present in the thigh. The femoral artery and vein are anastomosed end-to-end with interrupted 10-0 monofilament nylon on a 70-micron needle. Both the sciatic and femoral nerves are repaired with four 10-0 interrupted sutures. The remaining muscle groups in the thigh are then approximated with interruptible 4-0 absorbable suture. Lastly, the skin is closed by running 3-0 absorbable sutures. Rejection of the allografted limb is evaluated by two methods: 1) limb allografts are observed daily for visual signs of rejection such as erythema, edema, eschar-necrosis; and, 2) by a temperature decline in the limb as measured daily with a needle thermistor. A 5-degree C decline is defined as rejection end point. Representative histology will also be examined where appropriate.

Two to three centimeter square full thickness skin grafts between histoincompatible strains are also used as an end point in order to produce a larger number of animals to measure rejection reactions.

Results—The rat colony and the microsurgical techniques have been established along with a reliable skin graft model and an *in vitro* mixed leukocyte culture assay for evaluation for immune responsiveness of animals. We

have established the mean survival time of allogenic skin grafts as an end point against which to evaluate immune modifications on graft outcome. Baseline mixed lymphocyte culture responsiveness of naive rats against allogenic lymphocytes and the conditions for performing the assays have also been defined.

Future Plans—The allograft model described in this pilot project has now been integrated into research program #A618-RA entitled, "Prevention of Immunologic Rejection of Tissue and Limb Allografts."

[32] Development of HLA Class I Transfectants as Suppressor Cell Inducers: A Pilot Study _____

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Sponsor: VA Rehabilitation Research and Development Service (Project #A982-PA); Prosthetics Research Study; Pacific Northwest Research Foundation

Purpose—As part of an overall comprehensive approach to developing a tissue and limb allograft research program, this pilot proposal was initiated to develop expertise with the technique of class I gene transfection of normal lymphoblastoid cell lines in order to make HLA-defined transfected cell lines for use in studies of immune regulation in humans *in vitro*. Construction of autologous lymphoblastoid cell lines from normal healthy blood that express defined class I HLA antigens provides the reagents to test whether or not different class I HLA antigens in humans are able to preferentially induce suppression of the immune response. It also enables us to determine whether or not there is variation in the population in terms of the ability of different individuals to mount suppressor cell responses to the same HLA class I antigen. The rationale for these studies is that alloantigen-specific-suppressor T-cells appear to be important in the establishment of tolerance to allografts and one of the mechanisms through which the beneficial effects of donor-specific transfusions on kidney graft survival in rodent and human models is mediated is hypothesized to be through the development of these allospecific suppressor T-cells. As yet, the exact mechanisms and the inducer and target antigens responsible for the development of these cells is not known. Developing these defined cell lines would greatly facilitate investigations of these questions.

Progress—We were successful in transfecting defined HLA class I genes and getting them expressed in EBV-transformed lymphoblastoid cell lines from normal individuals. We have now established a panel of cell lines, grown them up in quantity and cryopreserved them for use in assays.

Methodology—Previously cloned HLA-A2 and HLA-B27 were inserted into a plasmid which contains the EBV

origin of replication sequence and a gene for drug resistance to hygromycin B. These vectors can then be inserted into EBV-transformed lymphoblastoid cell lines by the method of electroporation. The lymphoblastoid cells are then selected for resistance to hygromycin B by addition of that drug to the tissue culture medium. Growing cells are then cloned, grown up in hygromycin B and the expression of A2 or B27 confirmed by the use of antibodies to HLA-A2 or B27 with the appropriate fluoresceinated second antibody conjugate using the fluorescence-activated cell sorter. When grown up in quantity, a portion of these cells are cryopreserved in liquid N₂ and growing cultures are used as a source of cells to stimulate autologous peripheral blood mononuclear cells from individuals from which the cell line was derived. The prolonged (10-12 day) mixed lymphocyte culture is used to assess the development of suppressor responses.

Results—We have been able to successfully express both HLA-A2 and HLA-B27 in B lymphoblastoid cell lines. We have established/acquired 13 cell lines from people in the area who can be used as blood donors for further studies. Of these, eight have been successfully transfected with HLA-B27 and six with HLA-A2. Five of these cell lines are currently undergoing the transfection procedure and have not yet been fully analyzed.

Future Plans—Now that these transfected cell lines have been produced, these cell lines and the normal blood donors from which they were originally derived have been incorporated into research project #A618-RA entitled, "Prevention of Immunologic Rejection of Tissue and Limb Allografts."

[33] Prevention of Immunologic Rejection of Tissue and Limb Allografts

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Sponsor: VA Rehabilitation Research and Development Service (Project #A618-RA); Prosthetics Research Study; Pacific Northwest Research Foundation

Purpose—The overall goal of this project is to develop means by which to overcome the immunologic rejection mechanism so that we might transplant highly immunogenic tissue such as skin, bone, nerve, and composite tissues such as vascularized whole joints and whole limbs. Our goal is to develop conditioning regimes that will suppress the immunologic rejection reaction without producing unacceptable morbidity to the recipient. Clinical application of tissue transplants such as nerve, bone, and vascularized whole joints will be used in situations where the disability being corrected is nonlife-threatening. Therefore, existing immunosuppressive drugs and protocols for induction of nonresponsiveness to transplants are unacceptable because of their significant morbidity/side effects which are only acceptable for reversing a life-threatening situation. The main thrust of our research is to study the effectiveness of modified immunization with transplantation antigens with or without the concurrent use of new immunosuppressant drugs in immunologic models of allograft rejection reactions in the rat, dog, and human.

Progress—As a result of pilot funding, we have now established three allograft reaction models in which to assess the effects of manipulation of the immunization procedures on tolerance induction. Experiments are now underway to test effects of manipulation of alloantigen presentation to the recipient immune system in each of these three models to clarify mechanisms by which sensitization or induction of nonresponsiveness/tolerance occurs.

Methodology—For studies in humans, we are using B-lymphoblastoid cell lines (BLCL) from normal readily available blood donors which have had HLA-A2 or HLA-B27 transfected and expressed in them. These reagents provide us with the ability to test the target antigens and the inducers of T suppressor cells generated in mixed leukocyte culture (MLC) *in vitro* with human lymphoid cells under conditions where the target antigen is precisely defined. In the rat model, we have three end points with which to assess the effects of immune manipulation.

These are: 1) the *in vitro* lymph node MLC responses; 2) histoincompatible skin graft survival *in vivo*; and, 3) hindlimb allograft survival in the histoincompatible rats. In the dog, we have utilized the bone marrow transplant model to assess the effects of transfusion from donor animals into recipients followed by marrow grafting from the donor animal. This allows us to determine the effects of modifications of the transfusion product on graft outcome. We use either DLA-identical littermates to measure sensitization to minor histocompatibility antigens, or DLA-nonidentical dogs to examine the effects of major DLA transplantation antigen differences on graft outcome.

Results—Experiments using the HLA-A2 or B-27 transfected LCL as targets and inducers of MLC-generated T suppressor cells have been initiated, but as yet there are only preliminary results. That is, we can demonstrate that the transfected gene product is expressed on the cell surface of the LCL and that LCL act as efficient stimulators of normal donor blood mononuclear cells in MLC.

In the rat model, we have found minor reductions in recipient antidonor MLC responses after one donor-specific transfusion. After three donor-specific transfusions, there appears to be enhanced cellular activity *in vitro*. We are still evaluating whether or not this MLC reaction will be precise enough to pick up minor alterations in immune responsiveness induced by the transfusion procedures. In addition, we have found minor prolongation of unrelated skin graft survival with donor-specific transfusion, as has been reported by others. But we have found that the transfusion given in conjunction with the new immunosuppressant, FK-506, results in significantly prolonged allogenic skin graft survivals. Naive rats have skin graft survivals in the range of 9 1/2 days; after one donor-specific transfusion, it is 12 days. If they receive FK-506 I.M. at 1 mg/kg/day for 7 days before, and 7 days after the skin graft, survival goes up to 33 days; if they receive the same schedule of FK-506 and one donor-specific transfusion 7 days prior to the graft, survival is significantly increased to greater than 48 days.

In the dog model, we have observed that UV-B treatment inactivates the blood lymphocytes contained in the platelet preparation to the point where they do not sensitize (4 out of 4 engrafted versus 0 out of 4 expected). In addition, heat treatment of the blood at 45 degrees C for 45 minutes with additional treatment with low dose (2,000 cGy) radiation allowed successful engraftment in 8 out of 10 DLA identical littermate transfusion recipients. This result also was a significant improvement over the 27 out of 27 graft failures previously observed after three untreated transfusions. Unexpectedly, a control group of 10 dogs that received blood treated only with gamma irradiation resulted in nine engraftments. This data is consistent with low dose gamma radiation abolishing minor histocompatibility antigen presentation/sensitization in this dog model.

Further studies are needed to clarify the exact mechanism of this effect which has not yet been studied because this phenomenon has never been reported. Studies are currently underway to evaluate the same treatment protocols described above in the DLA-identical dogs, but instead to use them in DLA-mismatched and unrelated dogs, where the stimulus will be the major transplantation antigen barrier.

Future Plans/Implications—The synergistic effects achieved with FK-506 (the new highly effective immuno-

suppressant drug) are highly encouraging, and lead to additional study designs aimed at producing complete tolerance in this skin allograft model. The rationale is to optimize the suppressive regimes and condition for highly immunogenic skin grafts before applying them to the limb allograft model.

The finding that gamma radiation at low doses abolishes sensitization to minor histocompatibility antigens in this dog bone marrow transplant model is remarkable. This observation has not been made before. In addition, the fact that such low dose gamma radiation prevents transfusion-induced sensitization to minor histocompatibility antigens suggests that in humans, blood products should be gamma irradiated to prevent sensitization to these minor antigens. The magnitude of the effect of minor histocompatibility antigens/sensitization on solid organ and composite grafts is unknown, but would be estimated to be considerable, as skin allografts are known to strongly express these minor antigens, making it very difficult to induce tolerance to them.

Recent Publications Resulting from This Research

Treatment of Marrow Donor Blood Products with Gamma-Irradiation Prevents Transfusion-Induced Sensitization to DLA Identical Marrow Grafts. Storb R et al., in Transplantation Proceedings (in press).

[34] National Program for Automated Fabrication of Mobility Aids: Eastern Region

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Sponsor: VA Rehabilitation Research and Development Service (Project #A514-DA)

Purpose—The National Program for the Automated Fabrication of Mobility Aids (AFMA) is a research and development project being conducted at the VA Medical Center, New York, NY, in collaboration with the Prosthetics Research Study in Seattle, WA, and the Prosthetics Research Laboratory at Northwestern University in Chicago, IL. The purpose of this program was to conduct clinical developmental testing of computer-aided socket design and computer-aided manufacturing (CASD/CAM) systems for below-knee (BK) prosthetics. The software and equipment primarily being tested are those developed at: 1) the University College London (UCL) Bioengineering Centre (currently marketed by Nutem, Ltd.-ART, Inc., and by Applied Bioengineering Technology, Inc.);

and, 2) the University of British Columbia—Medical Engineering Resource Unit (UBC-MERU) (currently being marketed by Shape Technologies, Inc.). Clinical tests are being performed with these systems to determine the feasibility and benefits of AFMA technology in prosthetics, to obtain quantitative data to determine the efficacy of present CASD/CAM systems, to obtain data for further CASD/CAM system development, and to provide a limited introduction of CASD/CAM technologies to practicing prosthetists and other rehabilitation and health care professionals.

Progress—Clinical testing of the UCL/Nutem CASD/CAM system continued during the present project

period. To date, test sockets and definitive prostheses have been designed, fabricated, and fitted on 42 BK amputees. Five major software and four major hardware upgrades were obtained for the UCL CASD/CAM system. These upgrades have remedied most of the problems encountered and previously reported.

Software for the UBC-MERU/Shape Technologies CASD system was obtained in February 1990 and clinical testing begun. The UBC-MERU Canfit software is being tested in conjunction with the UCL/Nutem CAM equipment. To date, clinical trials on 10 BK amputees have been conducted.

Results from the clinical trials of both the UCL/Nutem and UBC-MERU/Shape Technologies CASD/CAM systems, together with the prosthetics, biomechanical, and physiological data on the test subjects compiled during the clinical trials have been input into a computerized relational database management system and analyzed: 1) to identify those areas/components of these systems requiring design refinement; 2) to obtain quantitative data for use in further research and development of prosthetics CASD/CAM systems; and, 3) to identify categories and characteristics of patients that can be successfully fitted and

those (if any) that cannot, using CASD/CAM techniques. A final report of the project results is being prepared.

In addition, preliminary tests were conducted using the Cyberware Laboratory optical digitizer for profilogrametric characterization of limb and stump spatial geometry and surface topography for CASD/CAM system input. Initial results are very encouraging.

Implications—The AFMA clinical trials demonstrate that CASD/CAM technologies can be effective, clinically viable tools that: 1) provide prosthetists with a means of quantitatively designing and fabricating sockets of consistently high quality; 2) enable prosthetists to expeditiously provide sockets accommodating amputee stump changes; 3) enable prosthetists to provide patients with exact duplicates, or precise, quantitatively modified variations of previous, well-fitting sockets; 4) provide prosthetists, physicians, and therapists with quantitative records and histories of the physiological, biomechanical, and prosthetics characteristics of patients; and, 5) provide a quantitative and efficacious aid for the education and training of prosthetists and other rehabilitative health care professionals.

[35] National Program for Automated Fabrication of Mobility Aids: Central Region

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Sponsor: VA Rehabilitation Research and Development Service (Project #A521-DA)

Purpose—The Prosthetics Research Laboratory of the Northwestern University/VA Lakeside Medical Center (NU/VALMC) in Chicago—in collaboration with the Prosthetics Research Study (PRS) in Seattle, and the New York University/VA Manhattan Medical Center in New York City—is involved in this cooperative clinical study of computer-aided design and computer-aided manufacturing (CAD/CAM) of sockets for below-knee prostheses. The purpose is to determine the efficacy of the present equipment and methods, and to uncover possibilities for refinement and improvement. The results should have a salutary influence on this newly emerging area of limb prosthetics.

Progress—As agreed by the participating centers, each center will fit approximately 40 amputees, for a total of 120 amputees through the computer-aided approach. We have invited several practicing prosthetists to participate

in the program; prosthetic laboratories from Illinois, Wisconsin, Ohio, and Tennessee have responded positively.

Thirty-six qualified below-knee subjects from our center and from participating prosthetics laboratories have been part of our clinical study. Eight VA subjects have participated. The sockets were designed using the equipment and techniques developed at the Bioengineering Centre of the University College London (UCL). Of these subjects, 31 have accepted the CAD/CAM sockets. Ten subjects accepted the socket on the first socket fitting, 13 on the second fitting, 7 on the third fitting, and one on the fourth fitting. The fitting failed for one subject after four socket trials. One subject died during the study. Twenty-three subjects have been issued the definitive limbs and are walking on the CAD/CAM-designed prosthesis. Socket fittings for the other subjects are in progress.

Aside from the UCL System, we also have the ShapeMaker software from the Prosthetics Research Study, Seattle, WA, and the CANFIT software from Shape Technologies, Inc., Vancouver, BC. We are in the process of evaluating these software systems. In general, we find the CAD/CAM systems being tested to be serviceable and adaptable to many below-knee residual limb shapes. We also found several aspects of fitting persons with below-knee amputations by CAD/CAM techniques to be considerably easier than when using conventional prosthetic techniques.

A promising new method for direct fabrication of solid models from computer-generated data is called stereolithography. Stereolithography, as developed by 3D Systems, is a laser-based instrument that forms solid models by utilizing a computer-controlled laser beam to cure a liquid photopolymer. The photopolymer solidifies when exposed to ultraviolet (UV) light. With this system, a three-dimensional (3-D) object can be formed directly from computer-aided designed data. Our laboratory, in collaboration with the Advanced Engineering/Design Center of Baxter Healthcare Corporation, in Round Lake, IL, has formed a prototype socket using stereolithography. This was a feasibility demonstration project. It suggests that in the future, sockets may be

formed directly, eliminating plaster carving and vacuum forming.

Results/Implications—We found several advantages in using the CAD/CAM system. The system provides what we term “controlled modification techniques.” Conventional prosthetic modifications make the measurement of build-ups and reductions very time-consuming. It is also difficult to return to the premodified shape. The CAD/CAM system enables the design of definitive sockets with respect to the number of plies of socks desired for fit. The software allows for the increase or decrease of size of the socket with reasonably accurate predictions of the resulting socket size. The CAD/CAM system not only makes accurately measured rectifications, it records them for future analysis. Both the socket shape and the history of socket modifications are recorded in the computer files. These records are useful for future reproduction of existing sockets, or for evaluation and analysis.

These are a few of the significant advantages we feel the CAD/CAM system provides to consumers and their prosthetists. Our experience with the system has been, in general, very positive. Further experience, coupled with continued modifications of the software, will further improve existing techniques.

[36] National Program for Automated Fabrication of Mobility Aids: Western Region

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Sponsor: VA Rehabilitation Research and Development Service (Project A504-DA)

Purpose—The purpose of this program was to assess, develop, and improve the computer-aided design and manufacturing technologies used in the fabrication of mobility aids.

Results—Use and testing of the University College of London (UCL) software has been phased out with the exception of finishing a few outreach subjects. Efforts have been focused on technology transfer to VA prosthetics clinics and the private sector.

Prosthetics Research Study (PRS) has a large body of information already collected in Automated Fabrication of Mobility Aids (AFMA) research trials. This information was gathered mostly from VA Medical Centers in the two years prior to finalizing data collection standards. As agreed at the March 1990 AFMA meeting, all previously completed questionnaire sets were recoded

onto the newly adopted forms. This meant that questions that had been added since the original drafts had to be left blank. Every effort was made to fill in the new forms as completely as possible, including recalling subjects for measurement. Forms for 38 subjects have been sent to New York for inclusion in their database. Ten subjects have to complete only the final evaluation form.

Current copies of the ShapeMaker software as well as user support and training have been provided to the two VA prosthetics services which have requested it: Hines and Seattle. Hines purchased digitizing and fabrication equipment; it has been operational since May 1990. Seattle VA purchased a computer and has a digitizer on loan from PRS. Socket fabrication will be provided by PRS on a research basis.

Seattle ShapeMaker Software Development. Both the ShapeMaker software and templates have undergone

continual improvement. Additions to the software have made it compatible with the stand-alone parallel interface digitizers available commercially. PRS has refined the application of AFMA to above-knee (AK) prosthetics. Both the AK template and Seattle Limb fabrication techniques have been remarkably successful. Seven of nine AK prostheses have been completed, with two in progress. The last three AK sockets required no changes in the design to produce a definitive prosthesis.

AFMap Software. At the request of the Chicago AFMA group, the AFMap software developed at PRS was altered. The file format change simplifies use of the AFMap data generated by analyzing relative tissue displacements occurring in sockets. The Chicago group has successfully used AFMap to provide basic information required for the development of finite element models of limbs of sockets.

Documentation Report. For the cooperative AFMA study, 40 subjects were required per site. As of Fall 1990, PRS had submitted 38 subjects. Of those, 2 were rejected, 26 were finished, and 10 are still in process. These were divided by 11 in-house subjects, 6 outreach patients, and 18 veterans taken from several of the VA Medical Centers. One of the two subjects rejected was a duplicate from another site and the second was a bilateral amputee and would not fit the research criteria.

PRS has submitted the following questionnaires: 1) all the release forms; 2) 15 of the 36 measurement charts; 3) all the Subject Initial and Prosthetist Initial Question-

naires; 4) 25 of the 36 Subject Initial and Prosthetist Initial Questionnaires; and, 5) all the Prosthetist Information Questionnaires. The remaining Evaluation Questionnaires will be submitted when the subjects are completed.

In-house and Outreach Measurement Charts will be submitted when the subjects are completed.

VA Medical Center subjects were transcribed from the initial study in which VA prosthetists did not receive measurement charts and there has been some difficulty in obtaining them. This is due to the following: two of the subjects have passed away, seven of the subjects were unable to reach a facility in order to be measured, and nine of the subjects' prosthetists have not responded to requests for data.

In the three years since the study began, PRS has fitted 466 BK amputees (464 adults, 2 children), and 20 AK amputees (17 adults, 3 children).

Education. June 10-15, 1990. In collaboration with the Northwestern University Prosthetics and Education Program, private prosthetists were introduced to the ShapeMaker and AFMap software.

June 20-28. PRS participated in the AFMA course given at the University of Texas, San Antonio.

August 7-9. PRS hosted two prosthetists from the Hines VAMC for advanced training in the use of the ShapeMaker software.

Fall 1990. PRS sponsored an AFMA course for VA personnel and others.

[37] CAD/CAM in Prosthetics: Direct Socket Carving

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Purpose—The University College London's Computer-Aided Socket Design (UCL-CAD/CAM) system enables a patient's socket to be produced, first as a computer representation, and then as a positive model carved by a numerically-controlled machine. Thereafter, the production of a socket involves the same methods of liner production and socket forming as with conventional procedures.

The process would be considerably shortened if the socket could be carved directly. One way would be to carve the socket shape out of a thick layer of liner material fitted inside a standard container. This would also speed up subsequent fitting modifications, since only a new

liner would be carved, retaining the existing socket and cosmetic cover. A feasibility study of this approach is being carried out, concentrating initially on the production of below-knee, patellar tendon bearing (PTB) sockets.

Areas requiring development are: 1) modifications to a standard carver to enable internal carving of the liner; 2) design of software to align the patient's socket and container, and to control the carving; 3) identification of a suitable material for the liner; and, 4) determination of the sizes and shapes of the standard containers.

Methodology—*Carver Modifications.* The carver's normal cutter, which is arranged perpendicular to the

axis of the carver, and carves the positive model from a solid block of material, was replaced by a high-speed cutter tipped with a two-bladed router bit, positioned on the axis of the carver so that the cutting head moves down inside the socket and cuts outward from the central axis. An extended shaft enables the cutter to reach to the distal end of a PTB socket about 12 inches in length.

Software Development. Parts of the program needed to be rewritten to align the socket to be carved with the standard container shape. Several approaches were considered, including aligning both with respect to their anterior tibial surfaces. However, the original method, which is to align them about a central axis, was found to have advantages, although it requires the container to be physically aligned in a jig on the carver. The proximal shape of the patient's socket is blended into that of the container to ensure an even liner thickness at the top.

Other changes enabled the socket to be carved from its proximal end, rather than distal as before, and modified the interference-checking algorithm which ensures that the cutter does not remove extra material when moving to a specific point on the socket.

Liner Material. Since parts of the liner will inevitably be thicker than in conventional sockets, ideally, the material used in this application should be lighter and stiffer than current liner materials. However, the only material found to date which satisfies other requirements, such as suitability for carving, resistance to compression over a period of use, and biocompatibility, is "PElite."

This is available in a maximum thickness of 1-inch, which imposes a limit on the allowable liner thickness at any point, and has implications for the number of standard containers that will be required.

Standard Container. The intention is to base the shape of the container on that of a normal leg, so that much of the cosmetic shape of the finished prosthesis will be automatically provided. A range of sizes would be used which were scaled versions of this shape. The optimum one would be selected for the patient, and the carved liner would then compensate for the differences in size and shape between socket and container. During the present experimental stage, 3 sizes of container have been used. It is envisaged that more, perhaps between 5 and 10, would eventually be used for a better cosmetic appearance.

Progress/Results—The modified software has been integrated into the existing UCL-CAD/CAM package, and a number of sockets carved. Three patients have been fitted to date, and the sockets were deemed to be comfortable. An alignment jig for the container socket which can be easily adjusted remains to be designed, and a more optimal alignment algorithm for aligning the computer socket model and container model needs to be devised. Problems remain with the thickness limitation of the PEelite liners and with the liner-blank forming process. The technique has shown to be viable under laboratory conditions; whether it is feasible as a commercial product remains to be determined.

[38] Functional Biomechanical Characterization and Functional Design Specification: Lower-Extremity Prosthetics

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Purpose—This project has two areas of emphasis. First, is the development of instrumentation and techniques for making biomechanical measurements and assembling visualization tools for the presentation of these data. Second, is the formulation and evaluation of models to test basic theories of human movement and prosthesis control in walking. The two areas are related in that accurate and reliable measurements are needed in order to test the validity of our models. In addition, the visualization tools also assist in the communication among engineers, clinicians, and users of prosthetic and orthotic devices.

Progress—Instrumentation. For motion measurement, what is wanted is a system for 3-dimensional (3-D) position measurement with high positional accuracy, fast sampling rate, real-time output, and the ability to distinguish and determine the position of a large number of markers. This laboratory has a machine that uses optoelectronic planar scanners to compute the positions of reflective markers. Unfortunately, the performance of the device does not meet our performance needs.

The first step was to characterize the machine by running some elementary tests, particularly related to the

scanner optics. The purpose of this was to examine the operation of the individual components *in situ*, so that idiosyncrasies could be accounted for at the time of measurement and later compensated for in any design modifications or enhancements. At this time, many of the characteristics of the individual scanners have been documented, and procedures have been developed to sufficiently determine the remaining characteristics.

In parallel with the hardware characterization, analytical techniques are being developed which will use redundant measurements to heighten the accuracy of the position estimates, while at the same time eliminating an existing problem with distinguishing multiple markers. The procedure uses statistical analysis to predict the maximum likelihood estimate of the position of any marker in 3-D space. The statistical nature of the technique results in data precision that exceeds the hardware/software precision of the individual scanners, and minimizes the variance of the data error. In addition to motion measurement, a system has been developed for monitoring the temporal characteristics of walking.

The final, necessary piece of instrumentation allows the measurement of reaction forces between the foot and the floor. For this purpose, two biomechanics platforms have been installed that give the 6-degree-of-freedom reaction at the floor (3 forces and 3 moments). Because the performance of these platforms will vary slightly depending on the particular installation, it was necessary to characterize and calibrate the platforms *in situ*. A loading apparatus was constructed to allow the application of

purely vertical loads of known magnitude at any desired point on a platform. A matrix of loading locations was mapped out on each of the two platforms, and measurements were taken at three different load magnitudes at each site. The data from these spatial/load calibrations will be used to filter data taken using the biomechanics platforms.

In addition to instrumentation, visualization tools are being developed for the presentation of biomechanics data. With these tools, video data can be combined with quantitative measurements or analytical results. For example, video recordings can be produced which will combine a television image with stick figures, ground reaction force mappings, data graphs, etc.

Modeling. The modeling efforts approach the biomechanics of prosthetics from two directions. On one hand, the mechanics of normal human walking are studied to gain a basic understanding of that activity. On the other hand, amputee interaction with and control of prostheses are studied to gain knowledge of the differences resulting from prosthetic replacement and an awareness of the problems that exist and possible solutions for those problems.

Recent Publications Resulting from This Research

Statistical Improvements in Accuracy of 3-D Triangulation for Human Motion Studies: Position Estimates from Redundant Light Plane Observations. Van Vorhis RL et al., First World Congress of Biomechanics, La Jolla, CA, 1990.

[39] Posturographic Assessment of Balance Reorganization in Patients with Peripheral Neuromuscular Lesions

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Sponsor: Nijmegen Institute of Cognition Research and Information Technology

Purpose—Our purpose is to develop a clinically valid posturographic procedure to assess the balance performance and reorganization of two different groups of patients with peripheral lesions: 1) lower limb amputees (acute disorder); and, 2) hereditary neuropathies (chronic disorder).

Methodology—Besides simple task conditions such as quiet upright standing, more complex conditions were implemented into the posturographic procedure to obtain

a better picture of the overall balance disability. Using an information processing theory, perceptual, cognitive, and motor variables were manipulated by changing the visual input, using a dual task paradigm, or by requiring anticipatory activity. Equipment included a dual plate force platform and an electromyogram (EMG).

Results—In lower limb amputees, complex task conditions provide additional and indispensable information about balance restoration, degree of automaticity, and

visual dependency in postural control. In patients with hereditary neuropathies, a dual task procedure revealed a temporary loss of balance automaticity when adapting to new rehabilitation footwear with ankle-stabilizing devices.

Implications—This research has shown that important information about sensory-motor reorganization may not be found when only relatively simple task conditions are applied in the assessment of gross motor skills, such as upright standing. This viewpoint has clear implications for rehabilitation methodology, particularly with respect to therapy evaluation studies. It is suggested that data obtained from gross motor assessment using complex conditions may reflect essential aspects of the motor skill

at a disability level as defined by the World Health Organization (WHO) in 1980.

Recent Publications Resulting from This Research

Balance Restoration in Lower Limb Amputees Assessed by a Visual Dependency Score. Geurts ACH et al., in Disorders of Posture and Gait, T. Brandt et al. (Eds.). Stuttgart: Thieme Verlag, 407-410, 1990.

From the Analysis of Movements to the Analysis of Skills: Bridging the Gap Between the Laboratory and the Clinic. Geurts ACH et al., J Rehabil Sci (in press).

The Value of Context Variation for Applied Motion Analysis. Geurts ACH et al., in Proceedings of the 8th Congress of the International Society of Electrophysiological Kinesiology. Amsterdam: Elsevier Science Publishers (in press).

[40] Ongoing Lower-Limb Amputee Database

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Sponsor: Tayside Health Board

Purpose—The aim of this project is to establish an ongoing database on lower-limb amputees admitted to the Dundee Limb Fitting Centre, providing statistical information on all lower-limb amputees, including medical, surgical, and social information, as well as information from the physiotherapy and occupational therapy departments.

Progress—A database has been established on amputees admitted to the Dundee Limb Fitting Centre since September 1965. The information initially collected was basic patient data, but has now expanded to include those elements described above. In addition, the date of death is obtained and included in the files.

Analysis of the information is ongoing, providing progress analysis of the amputee program and long-term amputee survival cases.

Methodology—A purpose-designed database has been developed using DBase 3+ software. The information is

collected during the admission of the patient to the Unit, and entered into the computer upon discharge. Readmission may require updating the information on the patient's file.

Results—Statistically-based figures are provided annually from the basic amputee medical/surgical information. These are used in lectures and publications, and also to monitor our rehabilitation program. Currently, 1,842 files are on record. Survival curves for amputees are currently being generated, demonstrating that the longevity of the amputee has increased significantly in the two decades 1970-79 and 1980-89.

Future Plans—It is intended to continue collecting information on amputees indefinitely, and modifying the database to include prosthetic information in the future.

C. Lower Limb

2. Above-Knee

[41] Geriatric Prosthetics: Design and Development of an Improved Above-Knee Socket

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Purpose—The purpose of this project is to investigate the prosthetics requirements of geriatric above-knee (AK) amputees, and to develop quantitative design procedures for prosthetic sockets for these amputees.

Progress—Work on measuring the physiological, biomechanical, and prosthetics parameters of 99 geriatric AK amputees and control subjects was completed. Analysis of the data compiled shows the following trends. All of the geriatric subjects tested, both amputees and non-amputee control subjects alike, evidenced symptoms of circulatory impairment. No common localized regions of poor circulation were observed, however, in the geriatric amputees tested. The thigh tissue mechanical elasticity measurements were anisotropic for all subjects tested. In general, the tissue elasticities measured were lower (less elastic) on the stumps of the amputee test subjects than on the thighs of the non-amputee control subjects. The stump tissue elasticities measured on geriatric amputees were lower, in general, than the corresponding stump tissue elasticities measured on non-geriatric amputees. In addition, no common local regions or common directions exhibiting higher or lower elasticity were observed for any of the subjects tested. With respect to sensory input and proprioception, 12 geriatric amputees evidenced slight sensory diminution in their stumps. But no major impairment was observed in these or any of the other amputee subjects tested, including those subjects amputated because of diabetes and peripheral vascular disease. Four of the geriatric amputees showed more localized stump tissue sensory diminution than any of the other amputees tested, but their sensory diminution was localized, and not of major consequence.

Work continued on AK socket design in conjunction with the above physiological and biomechanical testing. Investigations using tissue compliance measurements

with uniform cross-sectional loading for quantitative derivation of socket shape, as previously described, continued. Compilation of data on prosthetic loading, load distribution, and load tolerance ranges as a function of stump tissue compliance continued. Investigations of socket design versus energy and agility required for prosthesis donning and doffing, and effectiveness of prosthesis suspension were conducted. Work on development of socket instrumentation also continued. Prototypes of miniature shear stress transducers developed in the project were fabricated and installed in test sockets. Clinical tests to measure the static and dynamic normal and shear stresses at the stump/socket interface were begun.

Implications—Data have been compiled in this project quantitatively documenting differences in the tissue mechanical properties, circulation, muscular strength and endurance, and other physiological and biomechanical properties, prosthesis alignment and functional requirements, and stump/socket interface forces and moments between geriatric AK amputees and other, younger, more active amputees. Since the way prosthetic forces and moments are transferred to and from, and are distributed in an amputee's tissues is a function of prosthetic socket design, it follows that different design considerations should be used for geriatric amputees than for younger, more active amputees. The uniform force/tissue displacement procedures developed in this project have been shown to provide a first step in quantitatively achieving a more comfortable geriatric socket design. These studies demonstrate that socket design methodologies based on tissue mechanical and circulation properties are feasible and can produce more comfortable sockets. This has been shown to be especially important in the prosthetics care of geriatric AK amputees.

[42] Comparison of Four Types of Swing-Phase Knee Controls by Gait Analysis

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Sponsor: Commonwealth Department of Veterans' Affairs, Australia

Purpose—Gait analysis is part of our clinical evaluation of prosthetic componentry. Video recording of patients walking at known speeds on a treadmill, filmed against a 10-centimeters reference grid, provides the relevant coordinated spatial and temporal parameters.

Progress/Methodology—Three patients, unilateral above-knee amputees, participated in this study. All three were vigorous, active walkers, with long stumps. They were all fitted with AK prostheses with flexible sockets, universal Multiplex Mark V modular systems, Mauch S-N-S knee control units, and multiaxial feet. None of them spontaneously used the capability of the S-N-S for walking with a yielding knee after heelstrike.

The knee controls investigated were the Mauch S-N-S, the USMC Dyna-Plex, the Hosmer 55914 constant friction, and the Otto Bock 3R43.

The first three are interchangeable within the Multiplex V frame. For the Otto Bock 3R43, the socket of the prosthesis was transferred to an Otto Bock modular

system, with a multiaxial foot. The Mauch S-N-S controls were left for each patient at their usual levels of adjustment; other knee controls were adjusted to the patient's preferred resistance.

The patients walked at speeds of approximately 40, 50, 70, and 80 m/min. Symmetry of gait, expressed by the duration of the swing-phase and its percentage of the gait cycle was used as a comparison criterion.

Preliminary Results—Preliminary results indicate that for the speeds of 40, 50 and 70 m/min the rhythm of gait remains almost constant for each given knee control (including the constant friction one). Swing-phase dys-symmetry averaged 1.7% for the S-N-S, 2.6% for the Dyna-Plex, 6.5% for the Hosmer constant friction, and 11.6% for the Otto Bock 3R43. At 80 m/min, the Hosmer constant friction and Otto Bock 3R43 could not adjust to the speed. The Dyna-Plex swing dyssymmetry increased to 10.4%. Swing with the S-N-S control was symmetrical.

[43] Swing-Phase Control Mechanisms for Above-Knee Amputees

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Purpose—A number of studies have compared the performance of different swing-phase control mechanisms in an attempt to understand their functional benefits for the above-knee amputee. However, in doing so, none of these studies have held constant all the other variables of the prosthetic system, calling into question the validity of some of the conclusions. What is required is an adapter which allows a number of different knee systems (that is, knee-plus-shank units) to be attached to the same socket with the same static alignment of the knee and the same prosthetic foot. Tests carried out under these circumstances would minimize the effect of gait deviations from sources other than the differing knee systems.

Progress—Such an adapter has been designed and gait tests have been carried out on four different knee systems

for a single amputee. The four single-axis knee systems tests were: Blatchford internal coil spring, Blatchford pneumatic swing-phase control system, Otto Bock 3R15 constant friction system, and Otto Bock 3R44 hydraulic swing-phase control system, with a Blatchford Multiflex foot being used in each case.

Each knee system had its swing-phase characteristics set by a prosthetist to the subject's preference. The gait tests included bilateral kinetic and kinematic data for a single stride using a VICON system with simultaneous multi-stride recording from foot switches placed under both feet, and a goniometer placed across the prosthetic knee.

Results—Two-tail Student's *t*-tests with $p < 0.002$ show significant differences between all the knee systems for

the most temporal parameters examined. Consistent moment data about the joints of the contralateral limb for all four knee systems support the view that the amputee adjusted his cadence to suit the swing characteristics of the different knee systems. The fluid control systems showed similar maximum knee-flexion angle, as did the two friction systems with the two fluid systems showing

smaller and more normal values. The two Otto Bock knee systems exhibited similar swing periods, as did the two Blatchford systems. The flexion-extension cycle of the hip in late swing using friction knees, reported in previous literature, was confirmed. It was also seen, although to a lesser extent, with the fluid control knee systems.

C. Lower Limb

3. Below-Knee

[44] Efficiency of Dynamic Elastic Response Prosthetic Feet

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Sponsor: VA Rehabilitation Research and Development Service (Project #A517-RA)

Purpose—Following years of accepting the SACH foot as the optimum compromise between durability and functional effectiveness, as well as reasonable cost, several new feet with dynamic response (DR) qualities have been designed. However, apart from manufacturers' claims, the prosthetic team has no objective guidelines for prescribing DR feet. There are no criteria for selecting one design over the other. Nor is it known whether both the dysvascular and traumatic amputee will realize functional benefit from these new feet during normal community ambulation. The objectives of this study are: 1) to compare the efficiency of walking with the four DR foot designs to that of the SACH foot; 2) to define the influence of these designs on gait mechanics; and, 3) to evaluate the relative effectiveness of these prosthetic feet for the dysvascular and traumatic amputees.

Methodology—Tasks associated with community ambulation are being evaluated in the gait laboratory. Walking on ramps, stairs, and a level surface are being assessed under five different prosthetic conditions. The five designs being evaluated are the SACH, Flex-Foot, Carbon Copy II, Seattle-Lite, and Quantum. A total of 20 below-knee amputees (10 dysvascular and 10 traumatic) will undergo repeated testing resulting in 100 prosthetic fittings and gait analysis sessions by completion of the project.

A new prosthetic socket is made for each subject and is used for the duration of their participation in the study. The subjects wear each of the five feet for approximately one month prior to gait analysis. Thus, testing takes place over a 5- to 6-month period for each subject. The participants are kept blind as to the type of foot being worn to prevent subjective bias.

Electromyographic activity of six hip and knee muscles, kinematic, kinetic, and temporal characteristics of gait are collected during free- and fast-walking on level ground, as well as ascending and descending ramps and stairs. Ground reaction forces during the stance phase of gait are also measured during level walking for both the amputated and sound limb. In addition, the energy expenditure of walking is determined from the oxygen consumption monitored during a 20-minute self-selected pace walk.

Progress—Design and construction of a portable ramp and portable stairs suitable for use in the gait laboratory were completed.

To date, nine subjects have been provided with new prosthetic sockets. Twenty-four gait analysis sessions have been completed on seven subjects. Three subjects have completed all five prosthetic conditions; the remaining subjects are in various stages of the testing process.

Data processing and analysis is in progress on all subjects tested. Preliminary data analysis has been completed on one subject (DT) who has been tested with all five feet. The following findings are based on this single subject.

Ground reaction force data gathered during stance of the sound limb have demonstrated greater differences between the five prosthetic conditions than did the force data recorded during stance of the amputated limb. The magnitude of the progression force during loading and preswing was less with the Flex-Foot and Quantum than with the other prosthetic designs. The Flex-Foot also had the lowest vertical force in loading of the five conditions. These findings suggest a more controlled transfer of weight from the prosthetic limb to the sound limb with these two feet.

Analysis of the data gathered during ascending and descending a ramp indicated the trends between feet were similar to that of level walking. The Flex-Foot and the

Quantum had the greatest amount of dorsiflexion in late stance of all the feet tested.

Ambulation on the stairs resulted in more variation between feet during descent than during ascent. While descending the stairs, use of the SACH foot resulted in a longer gait cycle duration and total double-limb support time than the DR feet. This suggests that there is less stability on the stairs with the SACH foot. Also, knee motion with the Flex-Foot and Seattle-Lite foot approached normal flexion in early stance (20 to 30 degrees), more so than the motion recorded with the other feet.

Final conclusions regarding the performance of these five prosthetic feet must be reserved until data from all subjects have been analyzed.

Recent Publications Resulting from This Research

Below-Knee Amputee Gait with Dynamic Elastic Response
Prosthetic Feet: A Pilot Study. Torburn L et al., J Rehabil Res Dev 27(4):369-384, 1990.

[45] Gait Initiation in Below-Knee Amputees: Analysis of Safe Function

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Sponsor: VA Rehabilitation Research and Development Service (Project #A613-RA)

Purpose—The objective of this research is to investigate the transient movement phenomena associated with gait initiation in below-knee (BK) amputees. This study will record how variation in prosthetic alignment, speed of movement, and choice of initial swing limb (intact or prosthetic) affect the safety and efficiency of gait initiation.

The neuromuscular coordination necessary for balance maintenance and postural control is compromised in the amputee. Feedback channels including calf muscle spindle activity and ankle joint proprioceptive signals are lost. Since functional (daily living) activities require frequent transitions from stance to ambulation, amputees need to develop skills to safely negotiate the involved weight transfer and postural imbalances. This study will investigate the strategies the BK amputee uses to compensate for musculoskeletal asymmetry and will provide insight into the potential for gait training or prosthetic mechanical design to improve patient function.

Methodology—The ground reaction forces, center of pressure location, and lower limb electromyographic

activity will be monitored in three groups of subjects: 1) 20 age- and sex-matched normal controls; 2) 20 unilateral BK amputees with good ambulatory skills who will use an adjustable prosthesis for testing sessions; and, 3) 20 BK amputees wearing conventional prostheses. The subjects will stand on force platforms and begin walking at slow, normal, and fast speeds with their intact and prosthetic legs. Subjects with adjustable prostheses will have adjustments systematically made to their prosthetic limb (socket tilts and shifts, foot eversion/inversion and plantar/dorsiflexion, changes in prosthesis length) and will then repeat the gait initiation trials. Results of the normal and amputee populations will be compared and changes in gait initiation behavior with change in prosthesis alignment will be noted. Specifically, magnitude and direction of center of pressure excursion, magnitude and timing of peak vertical and shear ground reaction forces, and sequence of electromyographic activity including periods of antagonistic cocontraction will be recorded and used to evaluate the symmetry, safety, and efficiency of the movement preparation.

[46] CAD/CAM of Below-Knee Prosthetics: Program Studies

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Sponsor: VA Rehabilitation Research and Development Service (Project #A317-2RA)

Purpose—The first project uses finite-element analysis to predict pressures between a residual limb and prosthetic socket. Once a viable modeling technique is established, the procedure will provide a valuable tool for quantifying the nature of a good prosthetic fit as well as actually

aiding in the design of prosthetic sockets. The second project evaluates spatial foot positioning (alignment) for below-knee prostheses within a coordinate reference frame established from skeletal geometry.

[46a] Computerized Analysis of Below-Knee Socket Limb Mechanics

Progress—As reported previously, the use of constant dilatational elements to model the incompressibility of tissue in a linear analysis, coupled with the iterative removal of constraints on surface elements which go into tension, greatly improved the accuracy of the finite-element (FE) prediction of pressure to the experimentally measured pressure. As a final step in the validation of the modeling approach, another subject, fitted with an unrectified socket, and thus assuring total tissue/socket contact, has been tested. Measured pressures around the surface ranged from 5 to 30 psi for various alignments. Analysis of the FE model is underway.

The use of a generic model as a predictor of residual limb/socket pressures is also being evaluated for both unrectified and patellar tendon-bearing (PTB) rectified sockets. Scaling of the model for an individual is based on residual limb length, distal tissue thickness, and mediolateral and anteroposterior measurements at the proximal, distal, and tibial plateau levels. Socket rectification was implemented similar to that used in the UCL Computer-Aided Socket Design system, that is, radial modifications at frequently rectified local patches (fibular head, medial tibial flare, popliteal depression, patellar

tendon bar, etc.). Experimental verification of local interface pressures for multiple subjects is currently underway. Pressures are measured for multiple static loading conditions and for various alignments (5 degrees plantar flexion—5 degrees dorsiflexion), providing a sizeable database for comparison with FE predicted pressures.

Preliminary Results—We now believe that the careful use of the FE method can sufficiently describe the mechanics between the limb and socket. In addition to the proper representation of an incompressibility condition, the analyses seem sensitive to perturbations to the assigned stiffness of the tissue. This “stiffness” includes not only the modulus of elasticity of the tissue, but perhaps more importantly, the effects of the underlying tendinous and bony structures of the limb. Further work is being carried out in this area.

Implications—We have already begun work to integrate FE into the design of prosthetic sockets. Desired pressures will be input onto the surface of a model of a residual limb. The calculated shape will then become the rectified shape of the prosthetic socket.

[46b] Anatomically-Based A Priori Alignment Prescription Studies

Progress—In this analytical study, our goal is to first characterize what is acceptable prosthesis positioning in terms of loading patterns on the residual limb/prosthesis system during ambulation. Secondly, to use this information to position prosthetic components to allow a desired loading time course during an acceptable gait. Much of the effort has continued realizing and verifying hardware

measurement and analytical techniques which allow us to obtain accurate results from which confident conclusions can be drawn. Maximum likelihood statistical techniques have been implemented so position estimates benefit from multiple redundant observations. Techniques for establishing anatomical coordinate systems are being realized.

[47] The Diabetic Foot with Partial Amputation: A Biomechanical Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A573-RA)

Purpose—The purpose of this study is to conduct a retrospective biomechanical evaluation of diabetic veterans with successful partial amputations of the foot. Four groups will be formed according to the following levels of amputation: 1) hallux and first ray resection; 2) other digital and ray resections; 3) transmetatarsal amputations; and, 4) short transmetatarsal amputations, Lisfranc's and Chopart's procedures. Ten patients in each group will be studied. The shape of the partial foot will be measured. Traditional range of motion, strength, and deformity measurements will be taken, together with a battery of gait analysis parameters, including pressure distribution and kinematic measurement. Results will be compared with the "classical" opinions concerning the partial foot and a number of hypotheses with respect to deformity and function will be tested. The intact foot will also be examined to assess the presence of a number of putative risk factors.

Results of the study should lead to a better understanding of the partially amputated foot and a better definition of criteria that should be used for management during rehabilitation. Favorable results could be extremely important in convincing surgeons that a partial foot amputation is a viable procedure, thus resulting in the saving of many limbs that would otherwise have been amputated.

Methodology—A complete medical history, including a description of the surgical procedure(s), will be obtained for each subject prior to participation. Testing will be conducted during the course of one day and will be subdivided into four distinct stations: 1) collection of a detailed history of the subject's diabetes, measurement of sensation of each foot, as well as a vascular assessment; 2) the foot is thoroughly examined, the range of motion of the lower extremities is measured, and the degree of strength is determined (photographs and a bivalve cast of the amputated foot are also taken); 3) weightbearing A-P and lateral X-rays; and, 4) footprints, pressure distribution, and kinematic analysis.

Risk factors (such as sensation, peak pressure under the forefoot, joint mobility, and ankle-brachial vascular index) on the nonamputated side in these subjects will be

compared to age-matched diabetic individuals without ulcer or amputation. Data on healthy diabetic patients have been collected previously and are available in a database.

Sensory thresholds will be measured using monofilaments and vibration tests. Joint mobility measurements will include hallux dorsiflexion, subtalar total range of motion and ankle dorsiflexion. Independent *t* tests will be used to compare the two groups on each of seven different variables. In addition, a descriptive analysis of the contralateral and ipsilateral side in the patients with amputation will be made using the same variables. Pressure, kinematics, and radiographic measurements will be compared between the four levels of amputation. The group means for each criterion measure will be compared using a one factor analysis of variance.

Progress—The project team has had difficulty in identifying a sufficient subject pool at the VA hospital in Altoona, PA. Although at the onset of the study the search looked promising, the subject pool identified initially has been depleted due to subject expiration or to additional, more extensive surgery (such as BK amputation).

Future Plans/Implications—It will be necessary to go outside of the James E. Van Zandt VA Medical Center to other VA hospitals in the eastern United States to form a subject pool large enough to be statistically significant. An initial search has already begun at the VA hospital in Pittsburgh, PA, with others to follow at hospitals in West Virginia and Washington, D.C., among others.

Recent Publications Resulting from This Research

Plantar Pressure Distribution in Diabetic Patients with Charcot Neuroarthropathy of the Midfoot. Ulbrecht JS, Cavanagh PR, Diabetes 38 (Suppl 2):137A, 1989.

The Rocker Bottom Shoe: Pressure Relief for the Insensitive Diabetic Foot. Schaff PS, Cavanagh PR, Diabetes 38 (Suppl 2):80A, 1989.

Pressure Distribution Measurement in the Diabetic Foot. Cavanagh PR, Ulbrecht JS, in The Diabetic Foot, J. Sammarco (Ed.), (in press).

A Quantitative Approach to the Assessment of the Diabetic Foot. Cavanagh PR, Ulbrecht JS, in Disorders of the Foot. 2nd ed., M. H. Jhass (Ed.). Philadelphia: W.B. Saunders Company (in press).

[48] Clinical and Laboratory Study of Amputation Surgery and Rehabilitation

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Sponsor: VA Rehabilitation Research and Development Service (Project #A092-5RA)

Progress/Results—Prosthetics Research Study. Research and development of the Seattle-DVA below-knee prosthetic system has been completed. The socket is designed and fabricated of structural thermoplastics using automated computer-controlled techniques. Generic design templates and individually directed shape manipulations are accomplished using software programming prepared by us: Seattle ShapeMaker. Distal components consist of an intrinsic alignment device, ankle shank, and foot. Appropriate cosmesis has been developed and is available.

This prosthetic system was conceived to provide physiological force-movement vectors factored into the endoskeletal materials. Energy input and response, gravity-initiated, are physiologically programmed to body weight and activity level of the wearer. The limb is designed to be light, comfortable, energy-conserving, responsive, and essentially monolithic in construction, thus sharply reducing costs.

The DVA/BK prosthesis has been tested in-house extensively over the past year. It is now under field evaluation on 25 subjects at Edward Hines Jr., VA Hospital in Hines, IL. It was made available for veteran use and commercialization began around the end of 1990.

Ongoing prosthetics research continues with the development of a compatible prosthetic knee and above-knee (AK) socket to complete the Seattle VA lower-limb system. AFMA/AK socket design using the ShapeMaker Program is under way. Ten AK amputee subjects are participating in the "in-house" development and evaluation of the AK prosthetic system. We plan to complete this project during the 1991 fiscal year.

Automated Fabrication of Mobility Aids. The three-center study of CAD/CAM lower-limb prosthetic sockets has now concluded. Technology transfer of these techniques has proceeded rapidly. In addition to the several hundred amputees fitted during the course of this project, commercialization has paralleled our research. Installation of various components of the Department of Veterans Affairs (DVA)-developed system is in place in DVA Medical Centers. Private and institutional facilities in this country and abroad are beginning use of the system. The AFMA project is being aptly described as a revolution in a profession. Considerable international interest in this

research and development for application to the large unserved needs of Third World countries is being explored.

This research center participated in a number of training sessions and workshops on AFMA and VA Seattle Shapemaker during 1990. A national AFMA 4-day workshop took place in Seattle in October, 1990, sponsored by the DVA Rehabilitation Research and Development Service, Prosthetics Research Study, and the University of Washington.

Limb Viability and Amputation Surgery Techniques. Limb viability studies continue both for limbs at risk from peripheral vascular disease, diabetes, and other medical states, as well as limb salvage and/or amputation for primary trauma. The rapidly changing field of reconstructive limb salvage surgery following trauma has modified earlier thinking regarding limb salvage versus amputation. Guidelines are clouded. There is a need for clear-cut decision-making data and guidelines. Most of these individuals are young, and are seen initially in hospital emergency rooms and trauma centers. Vehicular and industrial accidents are primarily responsible. We have the opportunity at Prosthetics Research Study to statistically evaluate and carefully document a significant number of individuals being admitted to a major trauma center (Washington/Harborview) located a short distance from our research laboratories. Dr. Sigvard Hansen and Dr. Douglas Smith, together with Dr. Ernest Burgess, are conducting this clinical research. The information obtained is relevant to the military establishment.

We are continuing to study methods previously developed for tissue and limb liability evaluation through laboratory means. In addition to statistical information, the present basic research uses NMR spectrometry to study molecular activity of high energy phosphorus in skin. Dr. David Williams has developed a coil which isolates information received from the skin, which is the key tissue relevant to wound healing in the limb threatened by medical disease. The coil sufficiently eliminates "noise" from the deeper structures. As clinical information is obtained, this technique will be used as a laboratory tool to evaluate now-standard laboratory techniques such as TcPO₂ and PcO₂ measurements.

[49] Biomechanical Power Analysis of Prosthetic Feet: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A992-PA)

Purpose—Below-knee (BK) amputation results in altered gait biomechanics and an increased metabolic energy expenditure during walking. Recently there has been a focus on the development of improved prosthetic components to reduce the metabolic energy expenditure of ambulation and enhance the functional outcome following amputation. Energy-storing (ES) prosthetic feet, although initially developed to improve running and sports performance, have achieved widespread acceptance as an effective component to improve the walking gait of amputees. There is, however, little objective information regarding the influence of these feet on the biomechanics of BK amputee walking. As a result, guidelines for the use and prescription of these feet are empirical and vary widely. The purpose of this study was to determine the biomechanical adaptations used by the BK amputee to walk while wearing a conventional prosthetic foot-ankle assembly, and to subsequently evaluate the effect of ES feet in restoring normal gait characteristics.

Progress—Combined sagittal plane, lower extremity joint kinematic and kinetic data have been analyzed for five young amputee subjects during walking. Using an inverse dynamics linked segment modeling technique, calculation of joint moment, muscular power, and energy output have been completed for walking trials using three prosthetic feet: the SACH, SEATTLE, and Flex. An additional six elderly unilateral BK amputees have been studied during walking at natural cadences with each subject using four different prosthetic feet.

Preliminary Results—Energy generation during the pushoff phase of walking was diminished with all three prosthetic feet when compared to normal. As expected, the nonenergy-storing SACH foot demonstrated the least

energy generation, the SEATTLE intermediate, and the Flex the greatest.

Major differences were present in the knee power output characteristics of the amputee subjects. The normal eccentric knee extensor energy-absorbing phase which occurs after heel contact, and the subsequently following concentric knee extensor energy-generating phase were absent or markedly reduced in amplitude in the amputees. The loss of these power phases was the result of a reversal of the normal net knee extensor moment to a flexor moment.

With all three prosthetic feet, there was a marked increase in the magnitude and duration of the initial concentric hip extensor positive-power phase following heel-strike. This alteration represents one of the major biomechanical adaptations present in the BK amputee. Of particular note, there were no differences in the hip power outputs between prosthetic feet.

Future Plans/Implications—Of major importance is the finding that despite the improvements in the mechanical performance of ES prosthetic feet, no significant differences were found in the pattern or magnitude of knee and hip power outputs when compared to the SACH foot. Although a slight trend toward normalization may have been present with the Flex foot, it was anticipated that the increased energy generation of the Flex foot would have resulted in a reduction in some of the abnormalities noted while using the SACH foot.

Further analysis of the effects of prosthetic foot design on ambulation in the elderly amputee where walking speeds are slower is in progress. Studies are planned to assess the contribution of the intact limb and the swing-phase limb to the overall biomechanical adaptations that follow BK amputation.

[50] A Quantitative Method of Prosthetic Socket Construction for Below-Knee Amputees

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Sponsor: *Clynch Prosthetic and Orthotic Laboratory; Western Economic Diversification; Variety Club of Southern Alberta—Tent 61; Alberta Children's Hospital Foundation*

Purpose—The purpose of this investigation was to develop a quantitative method of constructing prosthetic sockets.

Methodology—1) An optical/laser digitizer collects numerical data describing the surface of the residual limb. 2) The numerical information for the residual limb is altered using a custom computer-aided design (CAD) software system running on a workstation. 3) Using the altered numerical data, a program is created for a numerically controlled (NC) milling machine. This machine mills out a positive mold. 4) The socket is constructed by laminating over the positive mold.

Results—Utilizing this method, we have successfully fit 15 patients. All the patients believe that their "computer-designed" sockets fit better than their conventionally made sockets. This subjective belief appears reasonable

since we can apply modifications with our custom CAD software that are virtually impossible utilizing conventional methods. Further confirmation of an adequate fit exists with the fact that these patients are wearing the sockets on a regular, full-time basis without complaint.

Future Plans—Additional clinical testing is necessary to further refine the procedures. In addition, an objective quantifiable method must be determined to evaluate the fit and comfort of the prosthetic socket.

Recent Publications Resulting from This Research

CAD/CAM of Prosthetic Sockets. Engsberg JR et al., Invited presentation at the Canadian National Society of the International Society of Prosthetics and Orthotics, Winnipeg, 1990.

A Quantitative Method of Prosthetic Socket Construction for Below-Knee Amputees. Engsberg JR et al., in Proceedings from The Summer Computer Simulation Conference, Calgary, 1990.

[51] Dynamic Alignment of Below-Knee Amputees

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Sponsor: *Dundee Limb Fitting Centre*

Purpose—Gait analysis has had some effect for a number of years on the dynamic alignment of below-knee amputees, but even with modern high-speed gait analysis systems it has proved inconvenient to wait for analysis between alignment changes, thus limiting its clinical role.

Progress/Methodology—By performing full kinematic and kinetic bilateral gait analysis on 32 established below-knee amputees while attending regular prosthetic clinics, it was possible to identify the fore-aft shear component of the ground reaction force as being a sensitive indicator of the quality of alignment. It was found that certain symmetrical criteria for this curve correlated closely with the amputees' own preferred alignment. This quality not only proved sensitive to alignment changes, but appeared to produce consistently repeatable alterations in shape for various alignment changes.

This study is concentrating on establishing the nature of the relationship between the shape of the fore-aft shear ground reaction curve and changes in prosthetic alignment. The subjects are provided with prostheses incorporating Berkeley Jigs to allow precise alignment changes to be made, and recording the alterations in the shape of the fore-aft shear ground reaction force for a complete range of alignment changes.

Implications—These tests will lead to the establishment of a rule-set governing the relationship between alignment changes and the shape of the fore-aft shear curve. If an adequate set of relationships can be established between them, it will be possible to predict the required alignment changes from the fore-aft shear curve. A system operating on this basis could be incorporated into the prosthetic prescription process.

[52] Biomechanical Evaluation of Energy-Storing Prosthetic Feet

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Sponsor: Dundee Limb Fitting Centre

Purpose—All lower-limb amputees require a prosthetic ankle-foot mechanism to be incorporated into their prostheses. Traditional designs of prosthetic feet have incorporated articulations which deflect the actions of the normal ankle/foot joints under load simulating. More recently, a range of nonarticulated ankle/feet have been developed which achieve their function by the deformation of their structural elements. This study evaluated the mechanical properties and the gait pattern of four energy-storing prosthetic feet (ESPF): the DYNAMIC foot, the CARBON COPY II foot, the SAFE foot, and the SEATTLE Light foot.

Methodology—Two test methods were followed: 1) mechanical tests involved the compression loading of the heel and forefoot parts of the prosthesis in order to analyze the load-deformation responses, and to calculate the input/output works and efficiencies; 2) clinical tests involved the gait analysis of an active unilateral below-knee amputee while wearing each of the four ESPF. The subject used each foot for one week prior to gait laboratory tests. These included force plate analysis, motion analysis, and joint moment analysis during normal walking.

Results—The compression tests showed that the heel parts had similar load response characteristics. The CARBON COPY II foot and the SEATTLE foot showed stiffer forefoot parts than the DYNAMIC foot and SAFE foot. The work efficiencies of the heels and

forefeet were higher for the DYNAMIC foot and the SEATTLE foot than for the CARBON COPY II and the SAFE foot.

It was evident from the clinical tests that the ankle moments for each prosthetic foot followed similar patterns to the normal joint moments. However, all the feet showed higher dorsiflexion and knee extension moments during push-off phase than the normal. The hip and knee moments produced by the prostheses were similar in pattern but different in magnitude to the normal moments during the stance phase. No significant differences were found in the joint moments during the heel strike.

It was concluded from the mechanical and clinical results that the prosthesis with the stiffest forefoot part (CARBON COPY II) produced the largest dorsiflexion and knee extension moments during the push-off phase, whereas the softest forefoot (SAFE) produced the smallest moments.

Future Plans/Implications—We hope to carry out a more detailed clinical study using several patients in order to derive a relationship between the mechanical and clinical tests. Eventually this information may be used to assist in prescription of the most appropriate prosthetic foot for an individual patient.

An investigation of the viscoelastic properties of the feet would also be required to produce a mathematical model of the prosthetic feet, so that their stiffness characteristics could be analyzed.

[53] Gait of Children Having a Unilateral Below-Knee Amputation

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Sponsor: Hospital for Sick Children Foundation; Variety Club of Southern Alberta—Tent 61; Alberta Children's Hospital Foundation

Purpose—The long-term goals of our research are to improve and then maintain the gait of below-knee-amputee (BKA) children. In order to accomplish these goals we have divided our research into three phases (description of gait, factors influencing gait, procedures

for improving gait). We have completed the data collection for Phase I and are in the process of analysis.

Progress—We performed a 3-D kinematic analysis of BKA children during both walking and running and

compared centers of mass (COM) and segment and joint angular orientations with those of typical children. In addition, we measured oxygen uptake and maximum vertical displacement of a marker representing the COM on three BKA (2 SACH foot and 1 Flex foot terminal device), and two typical children while walking on a treadmill.

Results—Results from the kinematic analysis indicated that the COM of BKA children was generally: 1) lower, relative to the ground; 2) farther forward relative to the midpoint of the hip joint centers; and, 3) positioned on the nonprosthetic side of the body during support when compared to that of typical children. This appeared to be due to: 1) greater hip and knee joint flexion; 2) more horizontal orientations of the trunk, thighs, and legs; and, 3) a trunk side flexion towards the nonprosthetic side of the body.

With respect to the treadmill study, the results for oxygen uptake and maximum vertical displacement of the COM seemed to separate the five subjects into two groups. The first group consisted of BKAs wearing a SACH foot terminal device and the second group consisted of the typical children and the child with the Flex foot terminal device. The first group generally displayed greater effort for three different walking speeds when compared to respective values in the second group.

Future Plans—The remaining data from Phase I will be analyzed and reported. We will then focus on Phase II, that is, to quantify the effects of six factors influencing the gait of BKA children: 1) socket shape; 2) prosthetic alignment; 3) prosthetic components; 4) BKA structure; 5) growth; and, 6) activity level.

Recent Publications Resulting from This Research

Comparison of Center of Mass between Below-Knee Amputee and Normal Children during Running. Aldridge KC, Engsborg JR, Harder JA, in Proceedings of the Canadian Society of Biomechanics, Quebec City, 1990.

Horizontal Locations of the Center of Mass for Below-Knee-Amputee Children during Gait. Engsborg JR, Patterson JL, Harder JA, in Proceedings of the American Society of Biomechanics, Miami, 1990.

Vertical Locations of the Center of Mass for Below-Knee-Amputee Children during Gait. Engsborg JR, Patterson JL, Harder JA, in Proceedings of the First World Congress of Biomechanics, San Diego, 1990.

A Function of Talocalcaneal Joint During Running Support. Engsborg JR, Allinger TL, Foot Ankle (in press).

Comparison of Effort Between Below-Knee-Amputee and Normal Children—Pilot Study. Engsborg JR, MacIntosh BR, Harder JA, J Assoc Child Prosthet Orthot Clin (in press).

External Loading Comparisons Between Normal and Below-Knee-Amputation Children During Walking. Engsborg JR et al., Arch Phys Med Rehabil (in press).

Timing Changes for Stance, Swing and Double Support in a Recent Child Below-the-Knee Amputee. Engsborg JR et al., Pediatric Exerc Sci (in press).

[54] Analysis of Metabolic Factors in the Gait of Congenital Below-Knee Amputees: A Comparison of the Seattle Foot and the SACH Foot

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Sponsor: National Health Research and Development Programme, Department of Health and Welfare, Canada

Purpose—The purpose of this study is to determine the extent to which the energy-conserving Seattle Foot permits more normal gait kinematics, dynamics, and energetics compared to the conventional SACH Foot for congenital, unilateral, below-knee amputees walking at their preferred cadence.

The specific goals are: 1) to quantify the effectiveness and efficiency of locomotion when wearing the Seattle Foot or SACH Foot; 2) to further the understanding of gait energetics when wearing a prosthetic foot; and, 3) to investigate the compensation strategies used by amputees to walk with prosthetic feet.

Progress/Methodology—In this 2-year project, assessments will be performed on 15 subjects who: 1) have congenital, unilateral below-knee amputations; 2) are between 10 and 19 years of age; 3) have a foot length greater than 22 cm; and, 4) are successfully fitted with a patellar tendon bearing (PTB)-type prosthetic socket.

Each subject requires a biomechanical and metabolic assessment for the Seattle Foot and for the SACH Foot. The biomechanical assessment consists of 10 walking trials, during which lower-limb kinematics are measured using the VICON motion tracking system. Footswitches are used to measure the timing of foot-floor contact.

Ground reaction forces are measured with a Kistler force platform. The three-dimensional kinematics, anthropometrics, and ground reaction force information are combined in an inverse dynamics analysis to determine joint reaction forces, net joint torques and powers for the hip, knee, and ankle joints, bilaterally.

The metabolic assessments are performed at Variety Village. Heart rate is monitored throughout testing with a standard three-lead electrocardiogram (ECG) configuration. Oxygen consumption, carbon dioxide production, and respiratory exchange ratio are being monitored using a Beckman Metabolic Measurement Cart (MM-1).

[55] Feedback at Heelstrike for the Primary Below-Knee Amputee

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Sponsor: Tayside Health Board

Purpose—Because of the absence of proprioception on the amputated side, some amputees are initially unable to perceive prosthetic heelstrike during walking. This means that initial contact tends to be further forward on the prosthetic foot, and for a below-knee amputee this leads to a rapid rollover with little weight being borne through the prosthesis.

Progress/Methodology—A study was carried out on a limited group of patients using a footswitch at the heel

with audible feedback. Gait analysis was used to confirm clinical observations and some promising results were obtained.

A more detailed study is currently being undertaken with the use of a limb-load monitor. It is intended to monitor below-knee amputees at the primary fitting stage for load bearing through the prosthesis. These subjects will be compared with a control group not using the limb-load monitor, and using gait analysis in order to assess the clinical benefits of feedback.

[56] Mechanical Properties of Soft Tissue

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Sponsor: Whitaker Foundation; Prosthetics Research Study

Purpose—We have used our designed instrumented pylon successfully with our interface normal and shear stress measurement system to collect clinical data on below-knee amputees.

Progress/Results—Results from walking trials show that shank pylon bending waveforms are similar for different subjects. This is also the case for shank axial force curves. However, pylon shear force waveforms are distinctly unique. Both peak magnitudes and waveform shapes differ between subjects. In addition, peak axial force and peak shear force in a step do not necessarily occur at the same time. Thus ratios between different force directions change significantly over the course of stance phase.

Future Plans/Implications—These subject-dependent differences in shank loading patterns during walking may

explain differences in anteromedial versus anterolateral interface stress patterns we have measured. To investigate this possibility we are developing analytical finite-element models of the residual limbs under clinical investigation and subjecting them to the shank loading conditions that we have measured clinically. A match between predicted and measured interface stress trends may provide us with an understanding of this "coupling" and better insight into interface stress tissue mechanics.

Recent Publications Resulting from This Research

The Residual Limb/Prosthetic Socket Interface: Normal Stress and Shear Stress. Sanders JE, Boone DA, Daly CH, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 234-235, 1990.

Stresses at the Amputee Residual Limb/Prosthetic Socket Interface. Sanders JE, Daly CH, First World Congress of Biomechanics, La Jolla, CA, 1990.

II. Biomechanics

For additional information on topics related to this category see the following Progress Reports: [42], [47], [146], [303], [313], [361], [367], [411], [614], [618].

A. Bone and Joint Studies

[57] Biomechanics of Patellofemoral Joint Disorders: In Vitro Human Cadaver Study

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Purpose—The patellofemoral force system is complex and considered to have a strong correlation with patellar disorders such as chondromalacia and subsequent arthrosis. The biomechanics of patellofemoral joint disorders that result from the problems associated with soft tissue or the tibia have been well-documented. However, the biomechanics of the patellofemoral disorders resulting from angular and torsional deformities of the femur have not been determined. The objective of this study was to determine the quantitative effects of fixed rotational deformities of the femur on patellofemoral contact pressures and the tension in quadriceps tendon in human cadaver knees.

Methodology—Seven fresh frozen cadaver knees were used. The specimens had no previous surgery, with macroscopically intact cartilage, radiographically normal bone structure, and intact joint capsule. The ages were unknown, but they appear to have been between 60 and 80 years old. The specimens were carefully dissected leaving only the femur, tibia, joint capsule, and quadriceps tendon. The femur and the tibia were then cut 25 cm away from the tibial plateau, and the fibula was eliminated. The specimen was clamped rigidly into steel cylinders and mounted onto a custom jig specifically built to be used in conjunction with an Instron machine. This system simulates fixed rotational deformities of the femur at various knee flexion angles and permits simultaneous measurement of the patellofemoral contact pressures and the tension in the quadriceps tendon.

Once the specimen was securely mounted and positioned at a desired knee flexion, the neutral position of

the patellofemoral joint was determined; then the patellofemoral contact pressures were measured under 200 N of tension in the quadriceps tendon using Fuji pressure-sensitive film (range: 0.2 to 2.0 MPa). For the patellofemoral contact pressures in rotated state, a new film was inserted and the tension in the quadriceps tendon was maintained at 200 N for 45 minutes in neutral position before rotating the specimen. The internal and external rotation of 20 and 30 degrees was accomplished at 2 rpm using a motorized assembly built into the jig while continuously monitoring the tension in the quadriceps tendon. The entire procedure was performed at knee flexion angles of 30, 60, 90, and 120 degrees. The contact pressures from Fuji film were quantified by using a calibrated scale from the manufacturer which was also verified in the laboratory by compressing cylindrical rubber discs with an Instron machine.

Results—The *in vitro* study revealed that the increase in the degree of fixed rotation of the distal femur in human cadaver knees resulted in a nonlinear increase in patellofemoral contact pressures on the contralateral facets of the patella (i.e., external rotation resulted in a contact pressure increase on the medial facet and internal rotation resulted in a contact pressure increase on the lateral facet of the patella). With the initial isometric tension of 200 N in the quadriceps tendon for 30, 60, 90, and 120 degrees of knee flexion, the peak contact pressure showed no significant differences between the medial and lateral facets of the patella in neutral position ($p > 0.5$). Upon 20 degrees of femur rotation, only a slight increase

was noted for the tension in the quadriceps tendon and the contact pressures in the contralateral facets of the patella. However, upon 30 degrees rotation, both the external and internal rotations of the distal femur resulted in significant increase in the tension of the quadriceps tendon and the contact pressures on contralateral facets of the patella. In addition, the external rotation for knee flexion angles of 30, 60, and 90 degrees showed significantly higher peak contact pressure increases on the

medial facet of the patella as compared to the internal rotation of the femur ($p < 0.05$). This study provides baseline information regarding changes in patellofemoral contact pressures that may be significant for the development of chondromalacia patella and subsequent arthrosis due to fixed rotational deformities of the femur. Further, surgical procedures involving osteotomies of the distal femur should only be performed after an accurate assessment of the femur rotation and angulation.

[57a] Biomechanics of Patellofemoral Joint Disorders: In Vivo Canine Study

Purpose—The objective of this part of the study was to determine the long-term response of the articular cartilage on the retropatellar surface to 30 degrees of fixed rotational deformities (internal and external) of the femur in a canine model.

Methodology—Fifteen skeletally mature mongrel dogs were used. Thirty degrees of fixed rotational deformities of the femur were surgically imposed using six-hole Dynamic Compression Plates on 12 experimental animals. Three remaining animals were used as controls. Twelve experimental animals were divided into four groups with three dogs in each group: bilateral internal rotations (3 and 6 months), and bilateral external rotations (3 and 6 months). All the procedures were performed bilaterally to insure even weightbearing. At the end of the experimental period, the dogs were euthanized and the hind legs were disarticulated at the hip and the ankle joint. Then all the musculature, ligaments, and menisci were carefully dissected away to expose the articular surface of the patellofemoral joint for indentation test. The unrelaxed (0.1 sec) and relaxed (2000 sec) shear modulus were determined for each quadrant of the retropatellar articular cartilage using a custom-built indenting apparatus (force of indentation = 0.98 N, diameter of the cylindrical ram indenter = 1.0 mm). The mathematical analysis was based on theoretical indentation mechanics of an infinite elastic layer bonded to a rigid half-space. The elastic layer corresponds to the articular cartilage, and the rigid half-space to the underlying bone. For this model, the analysis by Hayes provides an exact elastic solution for indentation by a plane-end cylindrical ram, assuming the shear traction between ram and the layer is negligible for small strains.

Results/Implications—For the *in vivo* canine study, the morphological examination revealed early signs of

arthrosis (redness of the articular cartilage) on the retropatellar surfaces at 6 months for both the internal and external femur rotations. The indentation tests showed no difference between each quadrant of the patella for all experimental groups regardless of the direction of the femur rotation ($p > 0.5$). However, a statistically significant decrease was observed for both the unrelaxed and relaxed shear modulus at 6 months for both directions of the femur rotation ($p < 0.05$). This was further supported by histological findings where the disorganization of the collagen fibers and blistering in the tangential layer were observed. These findings indicate that the cartilage softening occurred on patellar facets with both the increased and decreased contact pressures.

This study provides baseline information regarding changes in patellofemoral contact pressures that may be significant for the development of chondromalacia patella and subsequent arthrosis due to fixed rotational deformities of the femur. Further, surgical procedures involving osteotomies of the distal femur should only be performed after an accurate assessment of the femur rotation and angulation.

Recent Publications Resulting from This Research

- Influence of Fixed Rotational Deformities of the Femur of Patellofemoral Contact Pressures. Lee TQ, Bennett KA, Anzel SH, First World Congress of Biomechanics, I:61, 1990.
- Influence of Fixed Rotational Deformities of the Femur of Patellofemoral Contact Pressures—Human Cadaver Study. Lee TQ, Anzel SH, in Proceedings of the Western Orthopaedic Association, LA Chapter, 1990.
- The Influence of Fixed Rotational Deformities of the Femur on the Patellofemoral Joint: In Vitro and In Vivo Assessment. Lee TQ, in Proceedings of the 14th Annual Meeting of the American Society of Biomechanics, 1990.
- The Influence of Fixed Rotational Deformities of the Femur on the Patellofemoral Joint: In Vitro and In Vivo Assessment (Abstract). Lee TQ, J Biomech, 1990.
- Three and Six Months Assessment of the Articular Cartilage Resulting on the Retropatellar Surface Resulting From Fixed

Femur Rotation: In Vivo Canine Study. Lee TQ, Bennett KA, Anzel SH, in Proceedings of the First World Congress of Biomechanics, 1:60, 1990.

The Influence of Fixed Rotational Deformities of the Femur on the Patellofemoral Contact Pressures in Human Cadaver Knees. Lee TQ et al., Clin Orthop Rel Res (in press).

[58] Surgery Simulation Computer Models to Study Reconstructive Surgeries

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Purpose—Function can sometimes be restored to patients with movement disabilities via surgical reconstruction of musculoskeletal structures. Surgical reconstructions, however, often compromise the capacity of muscles to generate force and moment about the joints. Patients that cannot generate sufficient muscle force or joint moment are left with weak or dysfunctional limbs. The goal of this project is to understand the connection between the parameters of various surgical procedures and the force and moment-generating capacity of the muscles.

Methodology—We have developed a graphics-based model of the human lower extremity to simulate the effects of musculoskeletal reconstructions on muscle function. The lines of action of 43 muscle-tendon complexes were defined based on their relationships to three-dimensional bone surface models. A model for each muscle-tendon complex was formulated to compute its force-length relation. The kinematics of the lower extremity were defined by modeling the hip, knee, ankle, subtalar, and metatarsophalangeal joints. Thus, the maximum isometric force and joint moment that each muscle-tendon complex develops can be computed at any body position. Since the model is implemented on a computer graphics workstation, we can easily manipulate the model parameters according to various surgical techniques. For example, the origin-to-insertion path of a muscle-tendon complex can be graphically altered to simulate a tendon transfer. The results of the simulated surgeries can be displayed in terms of presurgery and postsurgery muscle forces, joint moments, and other biomechanical variables.

Results—We have applied our model of the lower limb to study tendon surgeries and pelvic osteotomies. Our analysis of tendon lengthenings indicates that the forces generated by the ankle plantarflexors are extremely sensitive to surgical lengthening of tendon; other muscles are much less sensitive. Quantifying the sensitivity of the

muscle forces and joint moments to changes in tendon length provides important new data needed to design effective tendon surgeries. Our simulations of the Chiari pelvic osteotomy suggest that osteotomies performed with high angulation shorten the hip abductors and may lead to the commonly observed weakness of the hip abductors. Our results show that horizontal osteotomies preserve the moment-generating capacity of the hip abductors and may therefore decrease the number of patients that limp after surgery.

Just as computer graphics systems have enhanced other areas of design and analysis, we have found that an interactive, graphics-based model of the human lower extremity is an effective new tool for designing and analyzing surgical procedures.

Recent Publications Resulting from This Research

- A Computer Graphics System to Study Human Movement. Delp SL et al., in Proceedings of the Twelfth International Congress of Biomechanics, 169-170, 1989.
- An Interactive Graphics-Based Model of the Lower Extremity to Simulate Tendon Transfer Surgeries. Delp SL et al., Adv Bioeng 167-168, 1989.
- Biomechanical Analysis of the Chiari Pelvic Osteotomy: Preserving Hip Abductor Strength. Delp SL et al., Clin Orthop 254:189-198, 1990.
- Computer Simulation of Lower Extremity Tendon Transfers. Delp SL et al., in Proceedings of the 36th Annual Meeting of the Orthopaedic Research Society, 537, 1990.
- An Interactive Graphics-Based Model of the Lower Extremity to Study Orthopaedic Surgical Procedures. Delp SL et al., IEEE Trans Biomed Eng 37(8):757-767, 1990.
- A Musculoskeletal Model of the Human Lower Extremity: The Effect of Muscle, Tendon, and Moment Arm on the Moment-Angle Relationship of Musculotendon Actuators at the Hip, Knee, and Ankle. Hoy MG, Zajac FE, Gordon ME, J Biomech 23:157-169, 1990.
- Understanding Human Movement with Computer Graphics. Delp DB, Delp SL, Soma: Eng Hum Body 3:17-25, 1990.

[59] Patient-Specific Finite Element Modeling of Bone from CT Scan Data

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Purpose—The objective of this project is to develop, verify, and document accurate methods for deriving the mechanical properties of inhomogeneous bone from computerized tomography (CT) scan data for the definition of three-dimensional (3-D), patient-specific finite element (FE) models. Several methods of evaluating the mechanical properties of the finite elements will be examined, including a new method based on the hypothesis that orthotropic mechanical properties of an element of bone can be derived by treating each element as a composite of subelements; each subelement would have a modulus computed from the fraction of bone in its volume. The accuracy of the modeling of the bone properties will be determined by comparing the predictions of FE models with the results of mechanical tests of bone specimens.

Methodology—The study is divided into two parts. In Part I, homogeneous specimens of human trabecular bone will be identified, CT-scanned, and mechanically tested. Existing relations for predicting the mechanical behavior of bone using CT scan data will be compared to the measured data. In addition, the new method for deriving orthotropic material properties of the specimens will be developed. This initial phase will establish the accuracy of predicting the behavior of bone of proven homogeneity, so that the techniques can be extended to the FE modeling of inhomogeneous bone.

Part II of the study will involve mechanical testing and FE modeling of inhomogeneous bone specimens. The existing and the newly developed relations for predicting the mechanical properties of bone from CT scan data will be used to generate several FE models of each bone specimen. Each specimen will be mechanically tested and its measured stiffness will be compared with the values predicted by its FE models. The accuracy and precision of each method of FE modeling will be assessed.

Progress/Preliminary Results—Software for automatically generating FE models of bone specimens from CT scan data has been developed. The various methods of computing the mechanical properties of bone will be incorporated into this program. Human tibiae and femora have been obtained for CT scanning/mechanical testing. A method of quantitatively assessing the 3-D homogeneity/inhomogeneity of the trabecular bone has been developed. This method, which uses quantitative computed tomography of the intact bone, is being used to identify regions of homogeneous trabecular bone for Part I of this study. The trabecular bone of the proximal tibia was found to be inhomogeneous; however, the degree of inhomogeneity varied greatly. Regions of relative homogeneity have been identified, and specimens for Part I of this study will be obtained from these regions.

Implications—These findings indicate that isolated specimens of trabecular bone cannot be assumed to be homogeneous. Property data that are obtained from tests of inhomogeneous specimens do not reflect the characteristics throughout the bone sample, and as such, these property data have limited applicability. In addition, the degree of inhomogeneity indicates that the mechanical properties measured from inhomogeneous specimens are highly sensitive to both the size and the precise boundaries of the specimens. These confounding effects can be minimized by using the above method to identify test specimens of the maximum possible homogeneity.

Recent Publications Resulting from This Research

Automated Three-Dimensional Finite Element Modelling of Bone: A New Method. Keyak JH, Meagher JM, Skinner HB, Mote CD, Jr, J Biomed Eng 12(5):389-397, 1990.

[60] Load-Bearing Characteristics of the Wrist with Intercarpal Arthrodesis

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Purpose—The specific objective of this study was to define the changes in load-bearing characteristics that occur with selective intercarpal arthrodesis.

Results—Radiocarpal, radioscapoid, and radiolunate loads have previously been measured in the presence of intact ligaments. Using the model of ligamentous instability suggested by Blevens, et al., scaphoid instability was simulated and radiolunate and radioscapoid articular loads were judged. In the presence of scaphoid instability, radiocarpal load distribution patterns are similar with both scapho-capitate and scapho-trapezial-trapezoid intercarpal arthrodesis. As in the model with-

out instability, scapho-capitate and scapho-trapezial-trapezoid fusions stiffen the radial column when the scaphoid is in the reduced position. Load is shifted to the radioscapoid articulation and away from the lunate fossa. The position of the scaphoid within the fusion mass profoundly affects the load transmission across the radioscapoid and radiolunate surfaces in the presence of instability. Palmarflexion of the scaphoid within the fusion mass unloads the radioscapoid articular surface. Extension of the scaphoid within the fusion mass unloads the radiolunate articular surface in the presence of instability. Additional investigations are not planned.

[61] Correlation of Streaming Potentials with Stages of Bone Repair/Remodeling

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Sponsor: VA Rehabilitation Research and Development Service (Project #A160-3RA)

Purpose—The processes of bone repair and remodeling are central to the welfare of patients after fractures and/or bone surgery, as well as in conditions ranging from spinal cord injury to osteoporosis, which affect the homeostasis of bone. While bone repair/remodeling is thought to be influenced by mechanical forces, the transducing signal that controls bone cell activity remains undefined. Circumstantial evidence points to mechanically induced fluid flow in bone, with concomitant production of streaming potentials (SP), also known as stress-generated potentials, as a possible control mechanism. While work on this phenomenon *in vitro* has been in progress for many years, *in vivo* studies of SPs in normal bone have only just begun and nothing is known of their occurrence or characteristics during reparative or resorptive processes. Although various mechanical and/or electrical systems are being developed or are in clinical use in attempts to affect bone healing as well as osteoporosis, the relationship of SPs to these treatment modalities remains unclear. This project aims to define how SPs relate to specific stages and types of bone healing and remodeling, as a step toward determining the clinical significance of these electrical signals.

Progress—The investigators previously developed a model for studying the magnitude and frequency dependence of SPs in living canine tibia using a regime of bending deformation (0.1-40 Hz) applied by a specially designed servohydraulic loading system. The SPs are measured by an improved design of Ag AgCl electrodes suitable for *in vivo* measurements during free walking, and during controlled tibia loading by the servohydraulic system under anesthesia. These techniques are in use in our other current work that seeks to relate existing SP data *in vitro* to *in vivo* conditions, and to study the effects of circulatory, biochemical, and structural factors on SPs in normal intact bone. Certain modifications of the techniques required to make measurements from our healing bone models *in vitro* and *in vivo* were necessary. During the first year of this project, these modifications were successfully completed and tested. Then measurements were initiated and completed on the 3-month series of the "drill hole model" (see Methodology) and work was initiated on the 1-month series. We anticipated all work on the drill hole model being completed as originally scheduled by month 18 of the project.

We also met with our collaborator, Dr. Goodship, and formulated definitive plans for work on our "osteotomy model."

Methodology—Using the techniques described, we measure SPs *in vivo* and *in vitro* on three different models in canine tibia. 1) Drill Hole Model: SP measurements during servohydraulic loading will be made at 2, 4, and 12 weeks during the healing process of 4 mm drill holes in canine tibia. The onset and nature of the SPs produced by bone as it fills the drill holes over time is documented and correlated with histological structure and porosity of the new bone. 2) Osteotomy Model: SP measurements on bone and callus during free walking and programmed servohydraulic loading will be made at 2, 4, and 12 weeks during healing of a 3 mm gap osteotomy stabilized with an external fixator (in collaboration with Dr. Goodship). SPs will be correlated with callus stiffness and histology. SPs also will be measured during several regimens of mechanical loading stimuli applied to the fixator that are thought to be of therapeutic value. Disturbances of the normal electrical patterns of SPs during bone regeneration that may be caused by placement of metallic fixation devices, or by artificial stimulation by microampere

currents, will be assessed. 3) Disuse Atrophy Model: After 6-weeks immobilization of one hindlimb, SPs will be measured as a function of the increased porosity of cortical bone in the immobilized tibia, in comparison with the contralateral limb exposed to continued weightbearing.

Results—Preliminary indications suggest that SPs from healing bone (3-month-old drill holes) may be larger than SPs from normal cortical bone. Data analysis on this first series of the drill hole model is incomplete.

Future Plans/Implications—This study represents a natural extension of our prior work on electrical stimulation of bone and on stresses at the bone implant interface, but with a new direction: characterization of SPs at specific clinical stages of bone repair/remodeling. This project joins our on-going studies in a two-pronged effort to understand the clinical significance of SPs and to use this knowledge to therapeutic advantage. This project has high significance with reference to surgical procedures, wound healing, and bony fixation of internal joints/prosthesis, as well as to all orthopedic surgical and rehabilitative treatment of musculoskeletal and neurological disorders in the aging veteran.

[62] In Vivo and In Vitro Mechanical Behavior of the Normal and Degenerated Lumbar Spine

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Sponsor: VA Rehabilitation Research and Development Service (Project #A095-4RA)

Purpose—The objective of this study was to characterize the static and dynamic load-sharing capability of the normal and degenerated lumbar spine unit. Analysis of the results will focus on the: 1) interdependence between disc and vertebral body properties; 2) degenerative conditions which compromise normal function; 3) development of clinical assessment techniques for predicting the mechanical condition of the human lumbar spine; and, most importantly, 4) role of mechanical dysfunction in chronic low back and sciatic pain. Based on these results, risk criteria will be developed for the management and prevention of low back disorders.

Progress—Chronic animal studies were designed to assess the chronic *in vivo* mechanical behavior of adult porcine spinal units following three-level rigid fixation and semirigid (constant load) vertebral body fixation. *In*

vitro mechanical and morphological studies of human vertebrae were designed to characterize the material and structural heterogeneity within the centrum and anterior longitudinal ligament (ALL).

Methodology—A specially designed loading apparatus was used to apply *in vivo* compressive loads to the porcine vertebral unit via pins inserted into the L1 and L3 vertebral bodies. Creep-recovery curves and cyclic load-deformation curves were obtained prior to and 1 to 4 months post surgery in a total of 16 animals. Anterior-posterior variations in the compressive stiffness of the vertebral end-plate were assessed along the sagittal plane using a specially constructed "continuous contact" loading apparatus, and the results were compared to sagittal plane variations in trabecular morphology and intervertebral disc hydration. The tensile mechanical properties

of the human ALL were assessed using a real-time motion analysis system which recorded the displacement of markers attached to the ligament substance and insertions.

Results—Comparison of the static (creep) and dynamic (cyclic) mechanical behavior of the chronic posterior fixation groups indicated that there was a significant decrease in creep rate and increase in stiffness in animals with rigid or semirigid fixation devices. The semirigid (constant force spring) fixation group, however, exhibited a lower stiffness and higher creep rate than the rigid (plate) fixation group, suggesting that less rigid fixation devices can provide a more graded fusion response.

Analysis of the trabecular morphology within the human vertebral centrum revealed a highly heterogenic distribution of trabecular bone in terms of stiffness, porosity, and orientation, suggesting that a heterogenic distribution of trabecular material should be used for analytical studies of the human spine. In addition, a close correlation between the compressive mechanical properties of the vertebral end-plate and disc properties was found, suggesting that an interdependence of disc and bone properties exists which is hypothesized to be an adaptive response to differences in disc pressure in normal and degenerated segments.

Large variations in regional strains in the ALL were found, with the highest strains in the outer part of the ligament. The mode of ligament failure was also correlated to the vertebral density, suggesting that ligament

structure and function are closely correlated to bone structure and function.

Future Plans—We are currently developing three-dimensional, anatomically correct finite element models of the human lumbar spine from CT data, MRI images, and tissue sections, and plan to develop analytical models which can be used to predict loads on the spine based upon force plate and skeletal accelerometer data. These models will be used to predict the mechanical behavior of the spine following aging, disease, injury, and surgical interventions. Longer-term chronic animal studies are also being planned and will include studies of biological fixation and bone remodeling using flexible or "ideal" stiffness anterior and posterior vertebral prostheses.

Recent Publications Resulting from This Research

Flexible Device for Vertebral Body Replacement. Main JA et al., *J Biomed Eng* 11:113-117, 1989.

In vivo Creep Behavior of the Normal and Degenerated Porcine Intervertebral Disc: A Preliminary Report. Keller TS et al., *J Spinal Disord* 1:267-268, 1989.

Regional Variations in the Compressive Properties of Lumbar Vertebral Trabeculae. Keller TS et al., *Spine (European edition)* 14:1012-1019, 1989.

Young's Modulus, Strength and Tissue Physical Properties of Human Compact Bone. Keller TS, Mao Z, Spengler DM, *J Orthop Res* 8:592-603, 1990.

The Dependence of Intervertebral Disc Mechanical Properties on Physiological Conditions. Keller TS et al., *Spine (European edition)* (in press).

Patents

Dynamic Vertebral Prosthesis. Patent Number: 4,932,975.

[63] Contact Pressure in the Hindfoot

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Purpose—The purpose of this study is to determine normative data on contact pressures in the human subtalar joint. This will then be used as a basis for further studies on pathological conditions and the investigation of our rationale of treatment for them. The specific pathological circumstances to be investigated include talar neck fractures, calcaneus fractures, and ligament injuries.

Progress—A loading system was developed and three circumstances were studied. First, the posterior facet

alone was loaded through the tibia. The posterior facet was used because it is the largest, most accessible and the most important. The load delivered through the tibia since this is the method used in other studies of this nature. We next repeated the study with the fibula under load as well and found that the significant loading differences occurred. We then applied load through the tibia and fibula and added transducers in the anterior/middle facet. No change occurred in the pressures or areas in the posterior facet with the addition of the transducers in the middle/anterior facet. We evaluated this as a measure of

the disturbance in specimen stability with the additional dissection required to gain access to the other facets.

Methodology—Fresh frozen cadaver specimens including a foot and 10 to 20 cm of distal tibia were used. Preparation of the specimen was done so as to maintain the integrity of joints. The posterior facet was approached posteriorly and the middle/anterior facet was approached medially. A loading apparatus holds the tibia while allowing the foot to move freely during application of loads up to 1400 N. The upper surface of the plate on which the foot rests can be adjusted to 10 degrees of hind-foot inversion or eversion. The amount of load applied to the fibula is monitored and adjusted from 0% to 20% of total applied load. Two Steinmann pins are inserted in the tibia, talus, and calcaneus to serve as the bases for a reference coordinate system in each bone. The coordinates of two points on each pin are located using a digitizing system based on rotary (RVDT) and linear variable differential transformers (LVDT). Displacement and angular position data are sampled using an analog-to-digital convertor interfaced to a computer. Relative translations and rotation between tibia and talus, and talus and calcaneus are calculated using custom software.

Pressure-sensitive film (Fuji Prescale) is used in the pressure measurement system. Dies corresponding to the shape of the joint surfaces are used to cut pieces of film which are sealed in waterproof tape. The film is positioned in the joint space before loads are applied to the

foot. Pressure causes dye-filled microspheres in one layer of film to break and be absorbed by the second layer of film. A video camera interfaced to a digitizing board is used to scan the film and calibration strips. A color map is produced on the computer monitor corresponding to the contact area and pressure distribution on the joint surface. The total contact area, overall average pressure, coordinates of the centroid of the contact area, and the zone of peak pressure can be calculated.

Results/Implications—Thirteen normal specimens have been tested. Analyses are currently being completed on pressure distribution and kinematics, and on the role of the fibula in load distribution in the normal subtalar joint. In general, the medial and anterior parts of the posterior facet were the most loaded regions. The overall contact areas increased with increasing loads. The high pressure zone increased more than the overall contact areas at the higher loads. In inversion, the overall contact area/joint area was significantly less than in the neutral or everted position. Unlike the posterior facet, the contact areas in the anterior facet are not dependent on the inversion or eversion of the hindfoot. Though the contact areas and high pressure area ratios do increase from the 350 N to 700 N loads, they are not increased by further loads. These results indicate that the hindfoot is less tolerant of the inverted position than of neutral or everted position. Further, these data provide a background against which pathological alterations of the joint may be measured.

[64] Finger-Force and Motion Apparatus

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Sponsor: *Dana Foundation*

Purpose—The purpose of this study was the development and use of apparatus to measure the force exerted by fingers and their motion in opposition to computer-controlled force and motion.

Progress/Methodology—We have constructed a computer-controlled motor-drive apparatus which measures the force exerted by a finger and the angular position of the finger. The data is digitized and stored as a function of time in the computer. The computer also exerts a programmable force and provides programmable position control. A semiconductor load cell moves in a

circular arc as it is pushed on by a finger and measures reaction force on the finger.

We investigated flexure forces of the index, long, and ring fingers of subjects in opposition to the motor-drive load cell. In one application, a subject exerts maximum force against the load cell as the device sweeps through a range of angles under computer control. This yields force as a function of angular position during motion at controlled rates. In other experiments, the subject exerts a target force against the computer-controlled device, testing the ability of the subject to sense and control the force. The device can be programmed to provide

a reaction force that is a function of time or of position; for example, it can simulate pushing against a spring. The device can be used to measure finger force and motion or to provide controlled exercise. It has been used to study the kinesthetic perception of force and the ability to control the force exerted by fingers. It has also been used to study forces resulting from the stimulation of muscles.

Recent Publications Resulting from This Research

Reflected-Force Feedback to Fingers in Teleoperations. Sutter PH, Iatridis JC, Thakor NV, in Proceedings of the NASA Conference on Space Telerobotics, Pasadena, CA, IV:65-74, 1989.

[65] Quantitative Functional Anatomy of the Human Shoulder

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Quantitative data on the musculoskeletal system of shoulder and arm are needed with a view to: 1) analysis of movements of shoulder girdle and arm, based on arm movement registration in activities such as wheelchair driving; 2) analysis of movements of the shoulder girdle and arm in activities of daily living (ADL) and vocational activities; 3) predictions of outcome of arthrodesis of the shoulder in patients with a lesion of the brachial plexus; and, 4) aiding interpretation of *in vivo* human palpation data.

Methodology/Results—The cadaver measurement data were used to run a model which is based on finite element analysis and comprised a dynamic version of this method (SPACAR). The model was used to describe the movements of the bones of the shoulder girdle and arm with respect to each other and with the trunk.

The data on muscles were analyzed: the estimated physiological transsections correlated well with muscle mass with some exceptions. Left/right differences were not found.

The accuracy of the model was tested. The location of the center of rotation of the humeral head was computed. The function of the coracoclavicular connections was analyzed from earlier determinations of the position of the bones of the girdle in relation to each other and to the trunk in various positions of the arm. The model was validated on values taken from patients with arthrodesis of the shoulder. Studies on the efficiency of muscular work while driving a hand-rim propelled wheelchair ergometer were conducted.

Future Plans—Use of the model in ergonomic problems is planned.

[66] Biomechanical Modeling for 3-D Analysis of Lifting

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Sponsor: *Italian Ministry for University and Scientific Research*

Purpose—The purpose of this project is to achieve a comprehensive description of kinematics and loads on the spine in regard to manual material handling. The work is aimed at analyzing different lifting techniques in which the dynamic factors and the rotation of the trunk play an important role.

Progress—A model of the human body consisting of the head, trunk, upper arms and fore-arms, pelvis and lower

limbs, has been implemented on a computer. The inverse dynamics problem has been solved for the anatomical segments above the lumbar tract, and forces and movements have been computed in relation to an intervertebral disk that can be selected between L3/L4 and L5/S1.

The model was tested by a sensitivity analysis in which the different anthropometric and dynamic factors have been changed to observe their influence on the final results. A validation of the model has been made by

analyzing simple movements in the sagittal plane (the only ones described in the literature), and by comparison of the results. Preliminary investigations on different subjects and different lifting techniques has begun.

Methodology—The main instrumentation adopted for this study is a motion analyzer based on the elaboration of signals from two TV cameras. Reflective markers are arranged on the subject in such a way that each anatomical segment considered can be identified by at least three nonaligned points. A force platform is used for measuring the external forces acting on the load. A schematization of the body segments is made on the basis of the rigid body theory. Three-dimensional (3-D) description of body movement is achieved by considering the translatory components of the movement of each center of mass, and the rotation of each segment, by means of the Euler angles. No reactions at the lumbar intervertebral disks are computed by solving the inverse dynamics problem. The compression force on the disk is obtained by a simple schematization of the musculoskeletal structure based on the concept of the muscle equivalent.

Results—A comparison between the spinal loads computed by a static method and those obtained dynamically has shown that in some circumstances the compression force on the intervertebral disk can be as high as 2.4 times the load computed statically. Furthermore, the shearing force on the disk is not negligible, and due to the

inadequacy of the disk to sustain shearing forces they must be closely monitored. The model schematization results from a sensitivity analysis that the orientation of the disk is one of the most important parameters for the estimation of normal and transverse components. Thus it is imperative to obtain reliable data on the disk orientation in the different phases of movement.

Future Plans—We plan to improve the model as a tool for predicting spine loads by: 1) an investigation into the relation between the external measurements and orientation of the intervertebral disk surface; 2) better definition of the anthropometric parameters (such as the mass and movements of inertia) of the different body segments; 3) an analysis of the role of muscles and passive structure at the lumbar level, and implementation of new algorithms to predict how the forces are shared between them; and, 4) investigation of the role of intra-abdominal pressure.

Recent Publications Resulting from This Research

Valutazione Biomeccanica dei Carichi Sulla Colonna Vertebrale Mediante Modello Tridimensionale. Frigo C et al., in Proceedings of the International Seminar "Lavoro e Patologia del Rachide," Milano, 1989.

Three-Dimensional Model for Studying the Dynamic Loads on the Spine During Lifting. Frigo C, Clin Biomech 5:143-152, 1990.

A Three-Dimensional Model for Spinal Load Computation in Dynamic Conditions. Frigo C, in Proceedings of the First World Congress of Biomechanics, San Diego, 1990.

[67] Evaluation of Osteoporosis by Ultrasound, CAT Scan, and Photon Absorptiometry

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Purpose—The diagnosis of advanced osteoporosis may be based on changes in the bone density, and/or by measuring cortical bone thickness, both of which are generally determined from roentgenological examination of bone. However, the roentgenological evaluation of osteoporosis is qualitative in nature, and it requires a minimum bone loss of 30% before an unequivocal roentgenological diagnosis of osteoporosis can be made. The aim of this study was to determine if cortical bone thickness and bone density can be measured accurately by ultrasound, computer-aided tomography (CAT) scan, and photon absorptiometry, and to compare their relative sensitivity.

Methodology—The cortical bone thickness and bone densities were measured at 16 locations of each femur using a computer tomography (CT) unit (Ohio-2020, Technicare). Thicknesses at the same locations were then measured by ultrasound using the pulse-echo technique. An immersion-type transducer (Dapco, SIH5) was used at a frequency of 5 MHz with a pulse-repetition frequency of 100 Hz. Both the specimen and the transducer were immersed in a water tank. Once these ultrasonic measurements were completed, the bones were sectioned, and the actual thicknesses at the same locations were measured with a micrometer. The bone densities at each location were also determined.

Progress—Cortical bone thickness and bone densities of embalmed human femurs and tibiae have been measured by ultrasound, CT, and photon absorptiometry. Fresh and embalmed human vertebrae and pelvis have also been evaluated similarly.

Results—The individual micrometer measurements made on 48 locations were compared with the corresponding ultrasound and CT data. The correlation coefficients between the actual thickness and the ultrasonically-measured thickness was 0.95, and 0.62 with the CT. We attribute the error in the CT data partly to the technique involved in the measurement (it can read only integral numbers) as well as to the subjective nature in selecting bone edges, and thus in positioning the electronic cursors. Variations between the actual bone densities for these samples were minimal, and it did not show significant correlations with the attenuation of ultrasound.

The results of the *in vitro* study suggest that ultrasonic measurement of cortical thickness is more accurate

than similar measurement by CT. Moreover, ultrasound does not use ionizing radiation, and it is significantly cheaper to use than the CT. Thus, ultrasound technique, when fully developed, may be more suitable for large scale screening for osteoporosis.

Future Plans—This study is being continued in order to compare the relative accuracy of ultrasound, CT, and photon absorptiometry methods in evaluating osteoporosis. Other mechanical methods, such as bone vibration, are also being developed as a means to quantify the integrity of bone *in vivo*.

Recent Publications Resulting from This Research

Ultrasonic and Vibration Methods to Measure In Vivo Bone Properties. Saha S, invited paper, presented at the ASME Winter Annual Meeting, 1989.

Bone Mineral Content and Load Carrying Capacity of Whole Bones (Abstract). Saha S et al., Abstracts of the First World Congress on Biomechanics, I:208, 1990.

[68] Establishing the Reliability and Validity of an X-Ray Measure for Shoulder Subluxation

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Purpose—The objective of this study is to test the reliability and validity of a new X-ray method of measuring shoulder subluxation. The method involves positioning the patient in a specially constructed chair and taking an X-ray from a standardized position. This will produce a uniform film from which angles and distances can be measured with precision.

Specifically, we will test: 1) the construct validity of the X-ray method by comparing the measurements obtained for patients with clinically-subluxed shoulders to those without any clinical signs of subluxation; 2) the concurrent validity of the X-ray method by comparing measurements obtained of subluxed shoulders with occupational therapist's clinical measures of shoulder subluxation; 3) the inter-rater reliability of positioning the patient in the chair by having two teams of therapists position patients and comparing the measurements obtained from X-rays of a patient's subluxed shoulder; 4) the intra-rater reliability of positioning the patient in

the chair by having the same team of therapists position patients twice and comparing the measurements obtained from X-rays of a patient's subluxed shoulder; 5) the inter-rater reliability of the X-ray reading by comparing measurements made by four therapists from a single X-ray; and, 6) the intra-rater reliability of the X-ray reading by comparing measurements made twice by a therapist from a single X-ray.

Progress/Methodology—Data was collected from 36 stroke patients who have subluxation on clinical examination, and 36 patients who do not. Patients who do not have subluxation participated in the validation phase (Objective 1). Patients who have a subluxation participated in the validity and inter- and intra-rater reliability studies (Objectives 2 to 6). Patients exhibiting a subluxed shoulder on clinical examination were randomly allocated to participate in either the inter-rater or intra-rater study. Patients in whom inter-rater reliability was to be assessed

were positioned for X-ray by each of two teams of therapists with a rest interval. Patients in whom intra-rater reliability was to be assessed were positioned twice by the same team of therapists with a rest interval.

The dependent variables, distance and angle of subluxation, were measured on a ratio scale. If the values obtained from the X-ray readings were normally distributed, then parametric statistics like the *T*-test, analysis of variance *F* test, Pearson's, or intraclass correlation coefficients can be used to test the hypothesis.

Preliminary Results/Implications—An interim data analysis using the data from 12 subjects with subluxation and 12 subjects without subluxation was completed in August 1989. Results of this preliminary analysis indicate that the X-ray measure is reliable and valid. Establishing the reliability of the measure will permit needed research into the effectiveness of therapeutic interventions for subluxation. Specifically, the effectiveness of shoulder supports commonly used in the treatment and prevention of subluxation may be investigated.

[69] Harvard-Massachusetts Institute of Technology Rehabilitation Engineering Center

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Harvard-MIT REC addresses the NIDRR Research Priority "Quantification of Human Physical Performance." Seven collaborative, interdisciplinary projects (listed below) involve rehabilitation engineering research personnel at the MIT Newman Laboratory for Biomechanics and Human Rehabilitation and clinical rehabilitation research personnel at the Biomotion Laboratory of the Massachusetts General Hospital and at the Veterans Administration Medical Centers at West Roxbury/Brockton and Jamaica Plain.

- Computer-Aided Surgical Simulation of Femoral and Tibial Osteotomy
- Patient Management and Rehabilitation Protocols Following Major Hip Surgery Based on Quantitative *In Vivo* Data
- Quantification of Human Motor System Adaptation and the Ability to Use Hand Tools by Upper Extremity Amputees
- Quantitative Assessment of Functional Electrical Stimulated Grasp Devices Using a Human Interactive Hardware Simulator Approach
- A Force and Movement Transduction System for Diagnosis and Treatment of Movement Disorders
- Multi-Degree-of-Freedom Manipulandum for Characterization of Motor Function and Optimization of Assistive Technology
- Quantitative Assessment of Posture and Balance Abnormalities.

All projects stress developing and evaluating scientifically-based, quantitative methods for assessing the physical status of handicapped persons and of therapeutic

efforts for defect remediation. Different projects address medical interventions, including orthopaedic surgery and physical therapy, and/or augmentative technology, including amputation prostheses, orthoses, and functional neuromuscular stimulation.

A theme common to all projects is the use of human-interactive computer-based systems for functional assessment of disability status. When employed diagnostically, such systems present performance criteria and data via "friendly" computer interfaces to the physician, rehabilitator, and/or subject. When the consequences of differential therapy are being evaluated, such systems emulate alternative assistive technologies using special-purpose hardware in conjunction with the computer system, thereby achieving physical interaction with the disabled person. Such quantitative assessment can critique, augment, and enhance more common and prevalent qualitative, subjective, medical, and rehabilitation assessments. Inherent in our approach is the conviction that mathematically expressible (and therefore, computer-manageable) models of augmentative technology, of aspects the disabled human and of device-human interaction can help diagnose the extent and character of disability and better define and evaluate proposed rehabilitation protocols and technology. All studies are directed toward practical augmentative technology and/or improved rehabilitation diagnosis and therapy.

Specific projects reported on in this issue are: "Measurement of the Degrees of Freedom of the Normal Human Knee *In Vivo*," and "Using Axodes to Compare *In Vivo* Knee Kinematics Measured Using Bone versus

Skin-Mounted Markers," in Chapter II, A. Bone and Joint Studies; "Quantification and Display of Musculoskeletal Anatomy," "Mobility Analysis," and "Musculoskeletal Modelling," in Chapter II, B. Human Locomotion and Gait Training; and, "Correlation of *In*

Vivo Synovial Joint Pressure Data With That From Posthumous Hemipelvis and Proximal Femur Including Pressure-Instrumented Endoprosthesis," in Chapter XI, Orthopedic Implants, B. Hip.

[70] Computer-Aided Surgical Simulation of Femoral and Tibial Osteotomy

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Purpose—In the hip joint, the degeneration of cartilage, synonymous with osteoarthritis, is usually focal and located on the superior region of the femoral head where it articulates with the acetabulum, the area loaded during the stance phase of normal level walking. In intertrochanteric osteotomy, the proximal section of the femur is transected and reoriented to move an area of good cartilage into the load-bearing region. The average 12-year life of total hip replacement has renewed interest in osteotomy since it is intrinsically conservative of joint tissue, compared with total replacement where the removal of much natural bone and the use of acrylic cement makes revision difficult. For the younger patient, a successful osteotomy can provide 5, 10, or more years of service before partial or total hip replacement is necessary. At the knee, proximal tibial osteotomy is indicated in patients with osteoarthritis of one tibiofemoral compartment producing varus or valgus deformity.

Methodology—The preoperative planning of either osteotomy procedure poses a substantial geometric and functional challenge to the orthopaedic surgeon. In current practice, planning is based on, at the most, biplanar X-rays of the affected region. Using a protractor, ruler, and grease pencil, the orthopaedic surgeon sketches on the two-dimensional X-rays a geometrical design of what is intrinsically a three-dimensional manipulation. In addition to the primary goal of cutting and reconnecting the fragments of the proximal femur or tibia to bring good cartilage into proper load-bearing, the surgeon must also ascertain that the proposed alteration will cause minimal interference with the normal ranges of motion about the joint. Further, he/she must be confident that the alteration or reorientation of the bone components has not significantly lengthened or shortened the skeleton across the joint, considering also the possible alteration

of the effective muscle or ligament lengths. Ultimately, the surgeon must be concerned with how the operation will affect, and hopefully improve, the mobility and grace of the subject in tasks such as normal level walking, stair-climbing, rising from a chair, etc. The magnitude and complexity of this design task undoubtedly explains, in part, the uncertain outcome of the procedure and represents a deterrence to more widespread practice of osteotomy.

Computer-Aided Surgical Simulation (CASS), addresses this surgical design problem as prototypical of many musculoskeletal alterations practiced in orthopaedic surgery. CASS borrows from the now well-established field of computer-aided design (CAD), adopting both commercially-available computer hardware and graphic display terminals and reinterpreting and augmenting CAD software.

Observation of surgeons and practice in orthopaedics suggests that the engineer-designer and the orthopaedic practitioner have much in common. They observe the circumstances of the situation and devise an idea for a solution. Whereas the engineer-designer now can carry out the exploration, iteration, and optimization of design concepts in consort with the computer, the surgeon practitioner is constrained to a single solution, the particular surgical procedure performed in the operating room, and then must await the recovery of the patient to observe the consequences. Validation is uncertain since many procedures are very patient-specific. Even with similar procedures, the surgeon must follow a series of patients before evaluation of outcome is possible.

In some aspects, CASS is significantly different from CAD. Whereas the engineer designs *de novo*, the surgeon must deal *a priori* with the patient-specific, complex geometry of the relevant skeletal anatomy. The surgeon devises a plan to sever, realign, and reconnect these

anatomical parts, then wants to explore the consequences of the changes, compared to the preoperative state of the patient. A further major distinction between the design engineer with a CAD system, and a surgeon simulating a procedure on the patient's anatomy with the CASS system, is the background and experience the respective operators bring to the computer system. The engineer is fluent in the geometric, mathematical, and physical implications of CAD manipulation and is familiar with computer hardware and software. The surgeon's relevant prior experience focuses on direct observation and examination of the patient and studying the X-rays. Therefore, the computer's graphic display must present anatomy and mobility to the surgeon in a manner consistent with his or her prior experience; and the means by which the surgeon manipulates the display and interprets the conse-

quences of changes must be as traditional and easy to learn as possible.

Results—Overall, CASS can be subdivided into three tasks: mobility analysis for presimulation recording and presentation of user-friendly, easily manipulatable and interpretable dynamic displays of the patient's movement patterns; patient-specific anatomical representations for the computer displays on which the surgeon will simulate and evaluate the procedure, and for the determination of body segment mass and inertial properties for dynamic analyses; and musculoskeletal modelling for the detailed mathematical representation of the skeletal, joint, and muscle system for pre- and post-simulation evaluation. These tasks are described as separate projects.

[71] Studies of the Strength Parameters in the Vertebral Body

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Purpose—The goal was to study parametrically the geometric and constitutive properties influencing vertebral strength and to identify the biomechanical parameters which are most critical to vertebral failure.

Progress/Methodology—A three-dimensional (3D) finite-element (FE) model of the third lumbar vertebral body was developed, including two major material groups: cancellous bone for the centrum, and cortical bone for the cortical shell and endplates.

To study the effects of geometric, material, and loading parameters, models were created as follows: 1) refinement of the initial geometry, including: *a*) a tear-drop cross section corresponding to the frontal and sagittal diameters; *b*) inward sloping of the side walls to represent tapering; and, *c*) biconcavity of the vertebral body. Each of these changes was made by using analytical approximations to alter the coordinates of the 3D mesh; 2) stiffening of the cortex in the central third of the posterior wall to simulate the presence of the posterior elements; 3) regional variation of the modulus of elasticity of the cancellous region, in correspondence with quantitative computed tomography

data; 4) separate reductions of the moduli of the cortical, cancellous and endplate regions, followed by parallel reductions of the three moduli, to simulate conditions existing in osteoporosis; and, 5) three loading conditions were studied: uniform, peripheral, and anteriorly eccentric.

The analyses were performed using ADINA, a general displacement-based FE code.

Results—The results obtained are being evaluated in terms of endplate displacement, compressive stress of the cortical shell, and von Mises stresses in the endplate and centrum. The results demonstrate the importance of an accurate description of vertebral geometry. Stiffening of the posterior wall affects the results to a minor extent only. However, when the modulus is reduced for each of the constituents listed above, the displacements and stresses are modified considerably. Information on the overall stiffness of the centrum is found to be more important than that of the regional variations in the stiffness. The loading conditions are found to affect the results obtained, especially the location of maximum displacement.

Future Plans/Implications—It is planned to complete the analysis of the models developed. When complemented by controlled *in vitro* strength testing, the results

should allow development of improved predictors of vertebral fracture risk.

[72] Analysis of Strength Reduction Due to Metastatic Defects in the Lumbar Vertebrae

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Sponsor: *National Institutes of Health; M.E. Mueller Fellowship and the M.E. Mueller Professorship in Biomechanics at Harvard Medical School*

Purpose—To address the problem of strength reductions associated with metastatic lesions in the spine, a three-dimensional (3D) finite-element (FE) model of the vertebral body was developed to study the effects of geometry, material properties, and loading conditions influencing vertebral strength. In this study, we modeled the structural consequences of lytic metastatic lesions under both uniformly distributed and anteriorly eccentric loading. The presence of superimposed osteoporosis was also studied.

Progress/Methodology—The geometry of the lumbar vertebral body modeled included the modified tear-drop shape of the cross section, tapering due to inward sloping of the vertebral walls toward the center, and biconcavity of the endplates. Two major material groups were considered: cancellous bone for the centrum, and cortical bone for the cortical shell and endplates. The metastatic defect was modeled in one of two ways: 1) as a prism, symmetrically located about the mid-sagittal plane; or, 2) as a sphere with varying sizes and locations.

To study the combined effect of lesion and general bone loss due to osteoporosis, the latter was first studied alone, with a reduction of the elastic moduli of the cancellous and cortical bone. To simulate a loading condition corresponding to bending forward, an eccentric load distribution was applied to the endplate. The analyses were performed using ADINA, a general displacement-based FE code.

Results—For the prismatic defect alone, the displacement and stresses are shown to increase considerably. However, when combined with osteoporosis and under conditions of eccentric loading, the increase is even more dramatic, with a factor of 8.42 for displacement, and of 3.18 for stress, exceeding the local bone strength.

Future Plans/Implications—It is planned to complete the analysis for the spherical lesion. Additionally, parallel *in vitro* experiments providing experimental data are planned. These should allow us to use our results to develop improved predictions of vertebral failure in the presence of metastatic lesions.

[73] Force and Stability Analysis of the Human Elbow

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Purpose—The long-term goal of this study is to address the problems of elbow joint dysfunction and reconstructive surgery. Biomechanically, in order to achieve a beneficial surgical outcome, it is important to characterize: 1) mechanical environment and requirements imposed on

the elbow joint in daily and recreational activities; and, 2) pathological motion loss, weakness, and instability. This defines the functional impairment to be corrected by reconstructive surgery.

A detailed analysis of the reconstructed elbow joint under these mechanical environments will allow definition of the objective benefits of the surgery and provide a basis for selecting a given procedure.

Methodology—Static and dynamic data on force and position of the upper extremity are acquired by an automatic data analysis system. Electromyographic data are also recorded. Normal test subjects perform a series of routine arm activities. Sophisticated computer models analyze the test results to predict force and torque values.

Progress/Results—Computer software programs have been developed which allow simultaneous collection of motion and load data using the Isotrak system and the Kistler force plate. The kinematics of the joint and the force and moment applied at the joint can then be calculated. The technique has been applied and its reproducibility tested for study of the forces and moments involved in the upper extremities during push-up exercise. The force and moment data at the elbow joint throughout the push-up exercise have been successfully obtained for one subject. Currently, experiments are being carried out on 10 normal, healthy, young male subjects to examine the effects of various factors which may affect performance during this exercise.

An experimental method which uses the Isotrak electromagnetic tracking system has been developed and calibrated for assessment of kinematic and kinetic performance of total elbow joint replacements. This method

allows comparison of kinematic and kinetic parameters of the intact normal elbow joint with those of the prosthetic joint. Kinematic parameters include the axis of rotation, joint laxity in valgus-varus and internal-external rotation; kinetic parameters include those of tendon excursion and moment arms of the major elbow flexors and extensors.

Future Plans/Implications—Joint constraint and stability performance will be used to compare the five selected designs of prostheses for elbow joint reconstruction and replacement, each of which is currently available and represents a unique design feature and concept. Experimentally, joint stability or laxity in cadaveric specimens with prosthetic replacements will be quantitated by using the joint kinematic analysis. Elbow joint movement will be achieved with simulated muscle loading as well as additional valgus-varus stress. Changes in the pattern and magnitude of the axes of rotation will be used to assess the joint constraint. In addition, the mechanical advantage of each muscle around the replaced joint will be calculated based on the tendon excursion and joint rotation. Sensitivity analysis will also be performed to analyze the effects of surgical placement of these prostheses and soft tissue reconstruction.

Recent Publications Resulting from This Research

Incorporation of Muscle Architecture into the Muscle Length-Tension Relationship. Kaufman KR, An KN, Chao EYS, J Biomech 22:943-948, 1989.

Physiological Considerations of Muscle Force Through the Elbow Joint. An KN, Kaufman KR, Chao EYS, J Biomech 22:1249-1256, 1989.

[74] Prediction of the Evolution of Bony Architecture

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Purpose—The objective of this research is the development of a finite element computational program for the prediction of the stress adaptation of the trabecular architecture of cancellous bone tissue. A method of predicting the temporal evolution of the trabecular structure of the cancellous bone tissue surrounding a bone prosthesis will contribute significantly to the improved design of bone prostheses, improved surgical placement procedures for implants, the understanding of biological fixation (e.g., porous ingrowth), and to other societal problems, for

example, osteoporosis and the effects of long-term space flight. This predictive model is to be based on data consisting of experimentally determined remodeling rate coefficients, and on data generated from human cancellous bone specimens by quantitative stereological and anisotropic elastic constant measurement.

Progress—We are approximately 18 months into the project, and on schedule. Analytical formulation of the model is complete and we have written the computational

code. A report of this work has been submitted for publication. This report contains the first model for the prediction of trabecular remodeling in which both the orientation and cross-section of the local trabeculae are considered. It remains only to use the experimental data generated at the University of Michigan to evaluate the remodeling rate constants.

Methodology—Our work is entirely computational and analytical. The data employed was obtained at the University of Michigan.

Results—Development of a model has been completed that permits the prediction of temporal evolution of trabecular architecture when the mechanical loading on the bone tissue is altered as, for example, in the case when a prosthesis is implanted. Some interesting and exceedingly simple results concerning the response of the mid-section of long bones to combined axial and torsional loading have been found. Specifically, it was found that if a thick-walled right circular cylinder capable of surface remodeling is subjected to an axial compressive load and a twisting torque, the remodeling patterns depend on whether the periosteal surface or the endosteal surface controls the limits of the remodeling process. It is shown that the effect of increasing the torque is always opposite to the effect of increasing the compressive load. Thus, similar remodeling patterns are obtained by increasing one type of loading and decreasing the other type of loading. These results were demonstrated in considerable generality, with a minimum of assumptions. Aside from the restriction of idealized cylindrical geometry, the only

assumptions are that the bone tissue is linearly elastic and that there exists a finite range of remodeling equilibrium stresses. In particular, the results presented are independent of the specific type of rule governing the temporal evolution of the bone shape.

Future Plans/Implications—Analysis of the experimental data will be completed to determine the remodeling rate coefficients and apply our program to the prediction of the stress adaptation of the trabecular architecture of cancellous bone tissue in simple situations.

Recent Publications Resulting from This Research

- A Resolution Restriction for Wolff's Law of Trabecular Architecture. Cowin SC, Bull Hosp Jt Dis Orthop Inst, 49:206-213, 1989.
- Errors in the Orientation of the Principal Stress Axes if Bone Tissue is Modeled as Isotropic. Cowin SC, Hart RT, J Biomech 23:349-352, 1990.
- Properties of Cortical Bone and the Theory of Bone Remodeling. Cowin SC, in Proceedings of the Symposium on Biomechanics of Diarthrodial Joints, 1st World Congress on Biomechanics, V.C. Mow, A. Radcliffe, S. L-Y. Woo (Eds.), New York: Springer, 1990.
- The Structural Adaptation of Bones. Cowin SC, Symposium on Mechanics Applied to Living Organisms, in Proceedings of the 11th U.S. National Congress of Applied Mechanics. Appl Mech Rev 43S:126-133, 1990.
- Candidates for the Mechanosensory System in Bone. Cowin SC, Moss-Salentijn L, Moss ML, J Biomech Eng (accepted for publication).
- The Mean Intercept Length Polygons for Systems of Planar Nets. Luo GM, Sadegh AM, Cowin SC, J Materials Sci (accepted for publication).
- A Note on the Anisotropy and Fabric of Highly Porous Materials. Cowin SC, J Materials Sci (accepted for publication).
- The Proportional Elastic Invariants for Anisotropic Materials. Sadegh AM, Cowin SC, J Appl Mech (accepted for publication).

[75] Growth of Cartilage In Vitro: The Role of Mechanical Factors

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Sponsor: National Science Foundation

Purpose—The long-term objective of our research effort is to identify the mechanical factors which are important in regulating cartilage growth and remodeling, and to elucidate the cellular mechanisms by which mechanically-mediated growth and remodeling occur. While abundant *in vivo* experimental and clinical evidence suggests that mechanical factors play an important role in mediating growth, the phenom-

logical nature of existing data make it difficult to identify how specific features of mechanical loading affect cellular behavior and, consequently, tissue growth. The research here exploits an *in vitro* model system—the neonatal rat mandibular condyle—in which tissue growth occurs to examine the direct relationship between applied loads and tissue growth and biosynthesis.

Progress/Methodology—Progress to date includes primarily baseline studies of growth and biosynthesis under free-growing (not mechanically-loaded) conditions. We are developing systems in which the physical environment can be reliably and quantitatively controlled.

Mandibular condyles are harvested aseptically from 2-day-old Sprague-Dawley rats and maintained in culture with daily medium changes. The "biological state" is determined from a combination of morphological and biochemical assays. *Size*: Specimen length and diameter is determined daily in unloaded specimens using photomicroscopy. Loaded specimen length is continuously measured as the displacement of the loading platen. *Synthetic Rate*: The incorporation of radioactive precursors over a 2- to 12-hour period is assessed using standard techniques: ^3H -thymidine for cell proliferation by DNA synthesis; ^{35}S -sulfate for glycosaminoglycan (GAG) synthesis; and ^3H -proline for protein synthesis. *Tissue Composition*: DNA and GAG content is determined, respectively, from the Hoechst 33258 and dimethyl-methylene blue dye binding assays.

Rat condyles ($N > 100$) have been explanted and maintained unloaded in culture for up to 5 weeks. The condyles increased in length at a rate of $\sim 120\mu\text{m}/\text{day}$ for the first week, and $\sim 60\mu\text{m}/\text{day}$ for the remaining 4 weeks. Commensurate increases in wet weight and GAG content were observed; the GAG content normalized to weight remained approximately constant in time, suggesting that the increase in length was achieved by production of a normal GAG-containing matrix. DNA content increased progressively with time in culture, although the proportional increases were not as large as for GAG and

tissue weight. GAG synthesis rates were relatively constant over the 5-week period, consistent with the constant increase in tissue GAG content. Parallel studies with serum supplemented medium (1% FBS) showed essentially identical results, suggesting that factors present in serum do not significantly affect tissue growth.

A loading device has been designed, constructed, and tested. It is a major improvement over previously reported devices because it allows the condyles to be subjected to constant (but adjustable) force, independent of condyle length. Condyle length is monitored continuously using a capacitive displacement measurement. Studies of condyles subjected to constant load are ongoing.

Future Plans/Implications—This research is directed at understanding the role of mechanical forces in the growth of skeletal tissues. The direct relationship between the observed macroscopic growth and biochemical parameters suggests this condyle system will be a very useful model in which nondestructive observations of the response to mechanical perturbations can be made. In order to achieve our ultimate objective of discerning the physical and biological mechanisms involved in mechanically-mediated growth, ongoing and future studies will allow comparison of the growth response to several types of physical stimulation. A complete understanding of this would allow us to predict tissue composition and morphology for given loading conditions. This clearly has implications to our understanding of physiological and pathophysiological growth processes, and to the development of therapeutic modalities.

[76] Electrical Properties of Wet Bone as a Function of Frequency and Microstructure

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Sponsor: National Science Foundation

Purpose—Electrical properties of fresh human bone have not been characterized for all three principal directions and for a wide range of frequency. In this project, we plan to measure the electric and dielectric properties (the specific resistance, specific capacitance, complex dielectric constant, and the loss factor) of fresh human compact and cancellous bones in the three principal directions and for a frequency range of 5 Hz to 10 MHz. The measured electrical properties will be correlated

with the microstructure, density, and mineral content of the bone samples.

Methodology—Specimens from above-knee and below-knee amputations were obtained shortly after pathological examination and had been maintained under refrigeration from post-surgery until examination. All soft tissue was removed, the bones wrapped, and stored in a freezer. The frozen specimens would then be thawed, unwrapped,

machined, and tested without being allowed to dry. Electrical and physical properties were measured with small samples being saved for histological processing. Electrical measurements were made using LCR meters (HP 4275A and HP 4262A) with measurements being made in all three orthogonal directions.

Results—All electrical and dielectric properties except the resistivity and the impedance were highly frequency dependent for the frequency range tested. All electrical and dielectric properties were transversely isotropic as the values for the longitudinal direction were different from values obtained for the two transverse directions, and properties in the two transverse directions were approximately similar.

Progress—Preliminary studies have been completed to determine the validity of the proposed method of measurement. Use of different types of electrodes have been

tested in order to minimize the electrode polarization effect. Measurement of the electrical properties of some human compact and cancellous bone samples have also been completed. The information on the electric and dielectric properties of bone obtained from this study will be helpful to: 1) analyze the current distribution amongst different tissues when electrical stimulation is applied for osteogenesis; 2) develop a mathematical model for the electromechanical behavior of bone; and, 3) optimize a previously developed noncontacting electromagnetic device for monitoring the *in vivo* properties of bone.

Recent Publications Resulting from This Research

Electrical Properties of Demineralized Bone. Saha S et al., Digest of Papers: Eighth Southern Biomedical Engineering Conference, 147-149, 1989.

Electric and Dielectric Properties of Wet Human Cancellous Bone as a Function of Frequency. Saha S, Williams PA, Ann Biomed Eng 17:143-158, 1989.

[77] Nondestructive Surface Detection of Cartilage Degeneration via Electromechanical Spectroscopy

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Sponsor: National Science Foundation

Purpose—The long-term objective is to develop a non-destructive surface spectroscopic technique for early detection of degenerative joint disease, sensitive to molecular level changes in connective tissue that cannot be detected by current radiological or magnetic resonance methods. The immediate goals are to measure electrical and mechanical properties of cartilage on intact joints using electrodes placed on the articular surface. The ability to characterize the spatial and temporal behavior of electromechanical transduction in articular cartilage may enable detection of early stages of tissue degradation such as in osteoarthritis.

Progress—Recent theoretical studies suggest that a standing wave of electric current applied directly to the *articular surface* can result in a bulk mechanical stress, measurable at the surface. This *current-generated stress* is produced by the same electrokinetic mechanism as streaming potential. Here, we report: 1) measurement of this phenomenon in cartilage using a surface electrode geometry; 2) the relation between the measured stress

and the amplitude and frequency of the applied current; and, 3) sensitivity of current-generated stress to changes in plasma glucose (PG) caused by chemical modification or enzymatic extraction.

Methods—Calf articular cartilage disks 800 μm thick and 7 mm diameter were harvested from the femoropatellar groove. The transducer is a 125 μm -thick laminated structure composed of piezoelectric film (Kynar PVDF Piezoelectric Film, Pennwalt Corp., Valley Forge, PA) and silver chloride stimulating electrodes. Each stimulating electrode is 1.5 mm \times 4.0 mm with 1 mm separation. The metalization pattern on the piezoelectric film has the same geometry. The electrodes impose a spatial standing wave of current density resulting in a similar standing wave of mechanical stress. This stress is sensed by the piezoelectric film. The electrode separation (half spatial wavelength) allows penetration of current to be on the order of cartilage thickness; with thinner, more closely spaced electrodes, current would be confined to the superficial region. Independent mechanical calibration

of the piezoelectric film as used in the transducer gave approximately 1 mV output per 1 kPa of applied stress.

Cartilage disks were held in unconfined compression at a constant offset stress of 50 kPa using a Dynastat spectrometer. The articular surface was held against the transducer and the other surface against a porous platen, so that one surface and the sides of the disk were in contact with a 0.05 M Na phosphate, 0.1 M NaCl buffer used previously in studies of trypsin digestion. A sinusoidal current density between ~ 0.25 and ~ 1 mA/cm², in the frequency range 0.025 to 0.5 Hz, was then applied to the cartilage via the transducer electrodes.

Results—The mechanical stress amplitude was measured as a function of applied current density and frequency for a series of normal cartilage specimens. The stress was observed to be proportional to current density and inversely proportional to frequency, consistent with the trends predicted by the poroelastic theory. In cartilage, the applied current causes electrophoretic displacement of the negatively charged PG/matrix toward the positive electrode, and an oppositely directed flow of positively charged interstitial fluid (electroosmosis). This combined motion generates the mechanical stress measured by the transducer. As the frequency is raised, these motions have less time to develop; the resulting stress amplitude is lower, consistent with experimental findings.

In another series of experiments, the mechanical stress was also measured as a function of buffer pH (adjusted by sequential addition of HCl after preequi-

libration at pH 8.5) for specimens subjected to 1 mA/cm² current density. The stress decreased dramatically at low pH. Decreasing pH in this region primarily neutralizes carboxyl groups of PG and collagen and, to some extent, may disaggregate PG aggregates rendering them more mobile. Both effects would decrease the electrokinetic coupling responsible for current generated stress, consistent with the trends of our data and previous streaming potential versus pH data. Addition of 1 mg/ml trypsin to the buffer at pH 7.2 led to a 78% decrease in stress amplitude by 5.5 hr; such trypsin treatment was found previously to extract 88-96% of the galactosamine and 75-91% of the glucosamine of adult bovine cartilage in 24 hr.

Implications—The pH and enzymatic extraction data suggest that surface measurement of current-generated stress may provide a sensitive means for detecting degradative changes or loss of FCD-determining matrix constituents. Theoretical analysis, supported by these data, suggests that a microfabricated, multiple-interdigitated electrode array could be used to vary the spatial wavelength as well as the frequency of the applied current; this may enable detection of focal changes at surface versus deeper zones of cartilage in intact joints.

Recent Publications Resulting from This Research

An Electromechanically Coupled Poroelastic Medium Driven by an Applied Electric Current: Surface Detection of Bulk Material Properties. Sachs JR, Grodzinsky AJ, Physicochem Hydrodyn 11:585-614, 1989.

[78] Measurement of the Degrees-of-Freedom of the Normal Human Knee In Vivo

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Sponsor: National Science Foundation

Purpose—Modelling is an essential tool for evaluating the dynamics and control of the human knee. A prerequisite to the development of a mathematical model of the knee is the complete characterization of the kinematics of the joint, in particular, the number of kinematic degrees-of-freedom. There is a dearth of detailed, confirmed lower extremity skeletal kinematic data reported in the literature. Much of the existing data are for only a single activity, level walking. Inadequate information about the motion of the knee under different movements and loads has led to the proposal of knee models ranging from a

single-degree-of-freedom to 4-degrees-of-freedom. This specific investigation addresses the kinematics of the normal knee. The ultimate goal of this study is an experimental data-based, mathematical model of the human knee capable of characterizing normal and pathological performance, evaluating current internal prostheses and external orthoses, and recommending new designs for knee augmentation or replacement.

Methodology—As the initial step in an investigation of the control of the normal and pathological knee, a set of

experiments to measure its kinematics for several different tasks was carried out with a single subject. Arrays of markers—infrared light emitting diodes (LEDs)—were mounted on skeletal pins and the TRACK kinematic data acquisition system used to measure the bone movements about the knee. Data were collected for activities including voluntary swing of the knee through its full range of motion, normal gait, and a pivoting motion common in athletics. Three-dimensional (3-D) marker coordinates were smoothed using the GCV-based algorithm of Dohrmann, and the rigid body orientation and position data were differentiated using a Lanczos filter to obtain velocities. The velocity data were then used to calculate the instantaneous helical axes (IHAs) of the different movements. The loci of the IHAs for a task define a pair of ruled surfaces, one in the fixed body, and one in the moving body. These surfaces are the axodes of the movement and are characteristic of the mechanism producing the motion. Fixed axodes for the different tasks were displayed on a Personal IRIS workstation.

Results—The results clearly show that normal knee motion is dependent upon the task being performed. The axode for the voluntary swing motion is that of a nearly planar movement with different trajectories for flexion and extension. Both normal gait and the pivoting maneuver are fully 3-D motions, each with a distinctly different sequence of IHAs. A joint or coupling such as the knee constrains the relative motion between two bodies. The allowable range of motions constitutes a screw system of

an order equal to the number of degrees-of-freedom of the joint. The order of the system is determined by the number of independent screws in the system. Techniques are available for evaluating the independence of screws in a system, and for determining an orthogonal basis for a screw system. The number of active degrees-of-freedom for each of the different tasks was evaluated in both ways.

Future Plans—A second bone-pin experiment is in final stages of preparation. To complement the TRACK position-measuring system, a 3-axis accelerometer will be mounted on each TRACK LED array. Kinematic data will be processed both by smoothing and differentiating the position data, and integrating the accelerometer input with comparisons thereof. Data will be collected over a greater range of movements than the prior original bone-pin experiment and very specific protocols will be employed.

Recent Publications Resulting from This Research

Automatic 6-d.o.f. Kinematic Trajectory Acquisition and Analysis. Antonsson EK, Mann RW, *J Dyn Syst Meas Control* 111:31-39, 1989.

Geometry of the Kinematics of the Normal Human Knee. Murphy MC, PhD diss., Massachusetts Institute of Technology, 1990.

Instantaneous Helical Axes of the Normal Human Knee in Vivo.

Murphy MC et al., East/West Coast Gait Laboratories Conference, San Diego, 1990.

Measurement of the Degrees of Freedom of the Normal Human Knee In Vivo. Murphy MC, Mann RW, in *Proceedings of the Symposium on Dynamics and Control of Biomechanical Systems*, 1990 ASME Winter Annual Meeting, Dallas, 1990.

[79] Using Axodes to Compare In Vivo Knee Kinematics Measured Using Bone versus Skin-Mounted Markers

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Sponsor: National Science Foundation

Purpose—Two problems inherent in biokinematic studies are: 1) whether skeletal motion is accurately measured by observing markers on the skin; and, 2) how to define body-fixed coordinate systems relative to skeletal segments. Typically, experimenters place markers on the skin over bony landmarks (i.e., locations where the skeletal members may be palpated through the covering soft tissue), with the implicit assumption that the marker motion is an accurate reflection of the underlying skeletal movement. Yet, several studies indicate that there are

significant artifacts from soft tissue motion in kinematics measured with skin-mounted markers. However, quantitative information on the relative motion between the skin and bone is not available.

Progress/Methodology—A program of experiments was initiated to quantify any differences between the three-dimensional *in vivo* kinematics of the knee measured directly on the skeleton, and corresponding measurements using several different schemes for mounting

markers on the skin. To compare the mounting methods, the same subject was used in all experiments, and the same tasks were performed. When comparing data from different experiments, consistency in the representation of the data is essential. Thus, kinematic representations such as Euler angles are not acceptable. Euler angles, as well as most other methods used in biokinematic studies, are dependent on how body-fixed coordinate frames are defined. Since the definitions of these coordinate systems with respect to the skeleton cannot be performed with consistency, a different type of representation must be used. By calculating instantaneous helical axes and studying the resulting axodes, assembled from these time-varying axes, a description independent of coordinate frame definitions was obtained.

The experimental data were collected using the Selspot optoelectronic motion measurement system, with infrared light emitting diodes (LEDs) used as markers, and the TRACK software. In the first experiment, the LEDs were mounted in groups of six on rigid, plexiglass arrays attached to skeletal pins placed directly in the tibia and femur of the subject. In subsequent experiments with the same subject, the arrays of markers were mounted on the subject using three different techniques: 1) taped directly to the skin over bony landmarks; 2) mounted on rigid, acrylic frames strapped to the subject's limbs; and, 3) mounted on molded, plastic forms held on the subject with a vascular stocking. Data were obtained for different tasks, including normal gait, and voluntary swing of the knee through its full range of motion.

Results—Results of the bone-mounted markers for a voluntary swing show a nearly planar motion with different flexion and extension trajectories. The taped-on markers gave the least accurate reflection of this pattern, while the third mounting scheme produced a good representation. For gait data, the directly measured kinematic data indicate a combination of planar motion and rotations about secondary axes. The skin-mounted markers showed a predominantly planar motion, and did not accurately measure out-of-plane rotation components. Discrepancies may be attributed to skin motion relative to the bone. Results thus far are for a single subject and need further confirmation.

Future Plans—A second bone-pin experiment will complement the existing database, and provide an opportunity to compare a wider range of skin-mounting methods for the marker arrays.

Recent Publications Resulting from This Research

- Automatic 6-d.o.f. Kinematic Trajectory Acquisition and Analysis. Antonsson EK, Mann RW, *J Dyn Syst Meas Control*, 111(31-39):517, 1989.
- Comparison and Analysis of Biokinematic Data Using Instantaneous Helical Axis Methods. Karlsson JOM, Masters thesis, Massachusetts Institute of Technology, 1990.
- A Comparison of In Vivo Knee Kinematics Measured With Bone and Skin Mounted Markers. Murphy MC et al., East/West Coast Gait Laboratories Conference, San Diego, 1990.
- Using Axodes to Compare In Vivo Knee Kinematics Measured with Bone and Skin Mounted Markers. Karlsson JOM, Murphy MC, Mann RW, in *Proceedings of the Symposium on Dynamics and Control of Biomechanical Systems*, 1990 ASME Winter Annual Meeting, Dallas, 1990.

[80] Dynamic Estimation of Joint Loading

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Sponsor: *Whitaker Foundation; National Science Foundation*

Purpose—The estimation of joint loads involves the calculation of joint forces required to generate a given movement. Hence, the knee-joint forces generated in the process of gait can be estimated by accurate measurements of the motion of the foot and the shank, and an estimate of the mass and inertial properties of these two segments. A general system for dynamic estimation of joint loads in multi-link systems is being developed. The system includes the WATRACK data-acquisition system in the Motion Analysis Laboratory, and kinematic transducers such as an angular rate sensor and a linear accel-

erometer, which are integrated into one unit for the determination of link kinematics. The kinematic measurements and estimates of the inertial properties of the link under study are used to calculate the joint loads required to generate a particular movement.

Progress—A well-controlled 2-degrees-of-freedom mechanical pendulum was constructed in order to evaluate this integrated kinematic measuring unit. The system was equipped with a series of strain gauges to directly record the joint loads. The measured joint loads were

compared to the estimates based on both the WATRACK system alone, and the integrated kinematic measuring unit attached to the center of mass of the pendulum.

Results—The results show that the kinematic variables using the integrated kinematic measurement are the most accurate and, therefore, the most reliable basis for estimating joint loading. With the rapid development of advanced technology, the use of transducers (such as

accelerometers and angular rate sensors), combined with displacement measurement to obtain the kinematic variables, presents an optimal and feasible solution for high-quality joint loads estimation.

Portions of this work were presented at the 13th Annual Meeting of the American Society of Biomechanics in Burlington, VT, in 1989. An abstract describing this work was published in the conference proceedings.

[81] Computer-Based Teaching Aid for Temporomandibular Joint Dysfunction

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Sponsor: *None listed*

Purpose—The purpose of this study has been to develop a computer-based teaching aid to assist general practitioners in the diagnosis of temporomandibular joint dysfunction and its differentiation from other medical disorders which might resemble it. A diagnostic computer program for clinical use has been developed, and the current work has been based on a variant of this in which additional corrective text has been included to guide the user through any number of fictitious patients.

Progress/Methodology—A suitable CAL program has now been developed, and has been used in postgraduate courses to show qualified general practitioners how to approach the problem of temporomandibular joint dysfunction. The current program is not intended as a complete diagnosis-and-treatment, but rather has been designed to lead the clinician through all of the relevant questions that should be asked, and finally to indicate whether or not the patient should be referred to a specialist center for further investigation. A strong indi-

cation of joint dysfunction will result in a suggested referral. The user is first required to enter personal details of a fictitious patient, and the program then queries the presenting symptoms, medical history, and other symptoms such as stress, etc., until it is able to make a decision regarding referral. Users may invent any combination of symptoms subject only to constraints of self-consistency (e.g., the program will not allow the user to report pain in one part then deny it elsewhere). In the new teaching version of the program, the user is offered extra explanatory text should inconsistencies arise. A charting of the dentition is included, and the program will provide upon request both a hard copy of the data and a suitable referral letter.

The system has been written in Basic for a BBC microcomputer, but IBM versions are also available.

Preliminary Results—Questionnaires returned after postgraduate courses have shown that the CAL program has been well received and is regarded as a very useful teaching aid.

[82] Capture and Analysis of Joint Sounds

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Sponsor: *None listed*

Purpose—The purpose of this study has been to develop a low-cost computer-based system for the capture of transient joint sounds, and to analyze these sounds for signs of disease or other joint malfunction. Concentrating

initially on dental occlusion and the temporomandibular joint, and using a low-cost personal computer with suitable signal interface, a second purpose of the study has been to examine the feasibility of using a standard

cassette tape recorder in the clinic, then replaying the recorded sounds into the computer for analysis at a later time, thus making the technique accessible to general practitioners in both medicine and dentistry.

Progress—A microcomputer-based system is now being assessed, and suitable software has been written to allow the capture of over 20,000 data points at a selectable sample rate in the approximate range of 1.5–67 KHz. The capture program is self-triggered once background levels have been assessed, and the signal envelope displayed on screen can be stretched or compressed by the software as desired. A plotter driver and built-in screen dump allow rapid production of hard copies of screen displays, and the captured signal can be saved to disc for later recall. Various problems with differences between tape-recorded and direct sounds are now being overcome, and attempts are currently in progress to include fast Fourier transform analysis in the software to shed light on the frequencies involved.

Methodology—The system being developed uses a BBC microcomputer to which is attached a Unilab interface (Unilab, UK). This low-cost interface is a general purpose signal input/output unit containing a fast analog-to-digital converter which allows rapid capture at a maximum sample rate of 125 KHz, although software restrictions in the current study reduce this figure by approximately a factor of 2. Signal detection is via an

accelerometer (Knowles Electronics, UK) rather than a microphone because it can be placed directly against the joint without picking up ambient noise. The captured signal is either fed directly to the interface and/or recorder, or may be preamplified if desired. The software is fully menu-driven, and allows the user to set a signal level above background for the automatic triggering of capture. Up to 30 captured signals can be stored on a 5 1/4-inch diskette. Cassette tape recorders being investigated range from tabletop variable speed models to personal tape player/recorders.

Preliminary Results/Implications—The working system is already showing occlusal sound envelopes as detailed as those produced previously by conventional microphone/chart recorder techniques, and computer manipulation of the captured signal is revealing more detailed information. Multiple tooth contacts can easily be detected, and may be associated with either poor occlusion or temporomandibular joint problems. Preliminary studies of other joints, such as the knee, have produced unexpected sound envelopes even in apparently healthy joints, and it has even proved possible to record the human heartbeat. The results of fast Fourier transform analysis of the captured sounds are awaited with interest, since they might well show how much of each signal is joint-based, and how much is due to natural skeletal and soft tissue resonance.

[83] Anterolateral Instability of the Ankle

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Sponsor: *None listed*

Purpose—This study was initiated to investigate the conditions required to produce instability of the loaded ankle following section of the anterior talofibular ligament. It has been shown that rupture of the anterior talofibular ligament can lead to chronic lateral ligament instability of the ankle. Laxity of the joint can be demonstrated by an anterior drawer sign and talar tilt. These tests, however, are performed in tension, but the unstable ankle exhibits instability in compression and should be investigated as such.

Methodology—Cadaver ankles were mounted on a special jig in order to load the ankle in a vertical plane. The position of the heel could be altered to produce loading

through the joint at any position from medial to lateral. The loaded joint was then cycled through a range of motion and the kinematics of the joint was studied.

Results—The instability demonstrated when the joint was tested in compression was anterolateral rotational instability. When the ankle was loaded on the lateral side of the joint, no instability was demonstrable until 100 nm external rotational torque was applied to the tibiofibular segment. However, with the joint loaded medially, spontaneous subluxation of the joint occurred.

Future Plans—Functional instability can be improved by proprioceptive rehabilitation of the peroneal muscle

group which would be expected to apply an internal rotational torque to the tibiofibular segment and so reduce the tendency of the ankle to anterolateral rotational

instability. It is proposed to investigate the contribution of this muscle group on the cadaver ankle subjected to compressive loading.

[84] Three-Dimensional Biomechanical Model of the Shoulder Mechanism

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Sponsor: *None listed*

Purpose—The purpose of this project is to develop a three-dimensional (3-D) biomechanical model of the shoulder and shoulder girdle with which the effects of orthopedic treatment in the shoulder region can be predicted. The study has been focused on the prediction of the consequences of a glenohumeral arthrodesis of patients with an arm lamed due to a brachial plexus lesion.

Methodology—With the help of the computer program Spacar, based on a finite element approach, the shoulder mechanism can be modeled as a spatial mechanism consisting of beam, hinge, surface, truss, and slider truss elements which describe the properties of the bones, joints, thorax, ligaments, and muscles, respectively. For quantification and validation of the model, the following measurements were executed: 1) the 3-D positions of the scapula and clavicle were measured at several elevation angles of the humerus with and without loading the hand (30 subjects); 2) the 3-D humerus motions of 18 subjects with a glenohumeral arthrodesis were measured with the help of two video cameras; 3) a cadaver study in which the positions of the bones, the attachments of both ligaments and muscles, as well as the shape of all articular surfaces of 14 shoulder specimens, were measured three-dimensionally; and, 4) with 12 surface electrodes, the EMG-activity of 7 muscles was measured during humerus elevation with and without loading the arm (12 subjects).

Progress—An inverse dynamic model of the shoulder mechanism, including 16 muscles, 3 extracapsular ligaments, and the scapulothoracic gliding plane, is largely completed. Muscles are represented by a number of

(straight or curved) lines of action. Several optimizing criteria are realized to estimate the muscle force. The 3-D motions of the shoulder mechanism are thoroughly analyzed. Axial rotation of the clavicle can be estimated by minimizing the rotations in the acromioclavicular joint.

The influence of the fusion position between the humerus and the scapula, as well as the role of the shoulder girdle muscles in positioning the hand after a glenohumeral arthrodesis, could be derived and analyzed by model simulations.

Future Plans—To get more insight into the cause of habitual subluxation of the glenohumeral joint, parts of the model will be used to investigate the control mechanism of the rotator cuff muscles by which the glenohumeral joint is stabilized. Further, the role of the muscles and ligaments will be analyzed by means of model simulations.

Recent Publications Resulting from This Research

An Adjustable External Fixator to Perform a Glenohumeral Arthrodesis. Nieuwenhuis FJM, Pronk GM, in *Progress in Bioengineering*, 170-173, J.P. Paul et al. (Eds.). Bristol: Adam Hilger, 1989.

The Consequences of a Glenohumeral Arthrodesis. Pronk GM, *J Rehabil Sci* 2(1):30-32, 1989.

A Kinematic Model of the Shoulder Girdle: A Resume. Pronk GM, *J Med Eng Technol* 13(1/2):119-123, 1989.

Modelling of the Shoulder Mechanism. Rozendal RH et al., in *Proceedings of the 12th International Conference on Biomechanics*, Los Angeles, 1989.

The Role of the Coracoclavicular Mechanism in the Motion Pattern Between the Scapula and Clavicle. Pronk GM, Van der Helm FCT, in *Proceedings of the 12th International Conference on Biomechanics*, Los Angeles, 1989.

B. Human Locomotion and Gait Training

[85] Development of a Sensory Substitution System for the Insensate Foot

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Sponsor: VA Rehabilitation Research and Development Service (Project #A383-DA)

Purpose—Our goal was to develop a reliable, cost-effective, and portable insole pressure measurement prototype device.

Methodology/Preliminary Results—Our goal has been accomplished. Our system allows the long-term recording (up to 2 hours) of pressure-time data during ambulation for each step from 14 pressure sensors located within the insoles during various daily living activities. The recorded pressure data are then fed back to the subjects through electrotactile stimulation to assist their gait.

The insole data-acquisition system is portable, battery-supplied, and book-sized. The HD64180 microprocessor has the capacity of 512 kbyte physical memory. This system can collect pressure data from 14 channels at a 35 Hz sample frequency for 5 sec/min over a 2-hour period. It can also continuously collect pressure data for 15 min. A portable electrotactile stimulator for sensory feedback has also been developed. The stimulator has 14 inputs from the insole sensors and 14 corresponding electrodes on a belt worn around the waist for electrotactile stimulation. It can be used alone or in conjunction with our portable data-acquisition system for feeding back the processed information to the subjects. This sensory substitution device can also be used as a mobility aid for the blind subjects.

We have been conducting several clinical studies including sensate and diabetic insensate gaits, plantar pressures during shuffling and normal walking, assistive devices (canes and crutches), sensory substitution, and fatigued gait using the data-acquisition system. We have collected pressure data through the portable unit from 17 sensate and 4 insensate subjects for 4 minutes of continuous walking during multiple trials (60 sensate, 40 insensate), to explore sensate and insensate discriminators. Ten normal subjects have been studied for evaluating plantar pressure differences during shuffling and normal walking. The plantar pressures during ipsilateral and contralateral cane uses have been obtained from nine normal

subjects as compared with normal walking. We are also examining data obtained during the fatigue gait of a 2-hour walk from eight normal subjects to find how normals vary pressure distribution pattern under the foot over time.

Future Plans—We plan to explore and identify those metrics that are significant discriminators between sensate and insensate gait. We will also evaluate the sensory substitution system as a blind mobility aide.

Recent Publications Resulting from This Research

- Analysis of Foot Pressure Waveforms. Mehta D et al., in Proceedings of the IEEE Engineering in Medicine and Biology Society, 11:1487-1488, 1989.
- A Capacitance Pressure Sensor Using a Phase-Locked Loop. Patel A et al., J Rehabil Res Dev 26(2):55-62, 1989.
- Comparison of Interlink and Hercules Sensors for Plantar Pressure Measurement. Patel A et al., Arch Phys Med Rehabil 70-A:100, 1989.
- A Conductive Polymer Pressure Sensor Array. Maalej N et al., in Proceedings of the IEEE Engineering in Medicine and Biology Society, 11:1116-1117, 1989.
- Design of a Portable Electrotactile Stimulator for Use in Sensory Substitution Applications. Onesti RJ et al., in Proceedings of the IEEE Engineering in Medicine and Biology Society, 11:1439-1440, 1989.
- Electronic Circuits for Capacitive Pressure Sensors. Patel A et al., in Proceedings of the IEEE Engineering in Medicine and Biology Society, 11:1437-1438, 1989.
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- Locating High Pressures on Plantar Surface of the Foot. Zhu H et al., Arch Phys Med Rehabil 70-A:98, 1989.
- Piezoelectric Sensor for Foot Pressure Measurement. Bhat S et al., in Proceedings of the IEEE Engineering in Medicine and Biology Society, 11:1135-1136, 1989.
- Pressure Distribution Beneath Sensate and Insensate Feet. Zhu H et al., in Proceedings of the IEEE Engineering in Medicine and Biology Society, 11:822-823, 1989.
- Sensory Substitution Systems for Insensate Feet. Wertsch JJ et al., Arch Phys Med Rehabil 70-A:48, 1989.
- An Umbilical Data-Acquisition System for Measuring Pressures Between the Foot and Shoe. Zhu H et al., IEEE Trans Biomed Eng 37(9):908-911, 1990.
- Asymmetry of Plantar Pressure During Normal Walking. Zhu H, Wertsch JJ, Harris GF, Arch Phys Med Rehabil (in press).

Foot Pressure Distribution During Walking and Shuffling. Zhu H et al., Arch Phys Med Rehabil (in press).

A Microprocessor-Based Data-Acquisition System for Measuring Plantar Pressures During Ambulatory Subjects. Zhu H et al., IEEE Trans Biomed Eng (in press).

Plantar Pressures with Contralateral Versus Ipsilateral Cane Usage. Wertsch JJ et al., Arch Phys Med Rehabil (in press).

[85a] Asymmetry of Plantar Pressures During Normal Walking

Jacqueline J. Wertsch, MD; Hongsheng Zhu, MS; Gerald F. Harris, PhD

Purpose—The purpose of this project is to study plantar pressure distribution during normal walking and analyze the asymmetry of plantar pressures between two feet.

Methodology—In-shoe plantar pressures were recorded from 10 normal subjects during 4 minutes of continuous walking to evaluate symmetry of right and left plantar pressures. A portable microprocessor-based data-acquisition system was used for data collection. All subjects (ages 23 to 40 years) walked on a 32 m walkway at a metronome-controlled cadence of 105 steps/min. Peak plantar pressures (average 142 steps per subject) under seven sensors of each foot were processed from the recorded pressure-time data and then summated for every step. An unpaired *t*-test with the *p* value of 0.05 was used to statistically evaluate the pressure differences between two feet.

Results—Of 10 normal subjects studied, five subjects showed significant differences ($p < 0.05$) between summated plantar pressures under right and left feet. Among them, three subjects had an average of 47% higher plantar pressures under the left foot than those under the right foot: two subjects had an average of 18% lower plantar pressures under the left foot than those under the right foot. Five subjects did not show significant differences ($p > 0.05$) between summated right and left plantar pressures. This study suggests that asymmetry of plantar pressures during walking can be seen even among normal subjects.

Recent Publications Resulting from This Research

Asymmetry of Plantar Pressures During Normal Walking. Zhu H, Wertsch JJ, Harris GF, Arch Phys Med Rehabil (in press).

[85b] Cadence Effects on Plantar Pressures

Jacqueline J. Wertsch, MD; Hongsheng Zhu, MS; Gerald F. Harris, PhD; Melvin B. Price, DPM, PT

Purpose—The purpose of this project is to evaluate the effects of different walking cadences on the in-shoe plantar pressures from normal subjects.

Methodology—We are using insoles, each instrumented with seven pressure sensors and a portable microprocessor-based data-acquisition system, for data collection. The sample frequency is 35 samples per second for each sensor. Seven sensors are located under the posterior heel, anterior heel, first metatarsal head, second metatarsal head, fourth metatarsal head, fifth metatarsal head, and the hallux. Ten normal subjects are chosen for our study. The height, weight, and leg length of each subject are documented. The subjects walk on a 32 m walkway

at cadences of 60, 70, 80, 90, 100, 110, and 120 steps/min. All cadences are kept consistent with the use of a metronome. The *t*-test will be used to compare plantar pressures at different cadences.

Progress—This project is ongoing. To date, five normal subjects have been tested. Preliminary data indicate that there is an increase in plantar pressures as cadence increases. At low walking cadences, there is an unsteadiness during walking. Peak pressures, pressure-time integrals, and foot-to-floor contact durations at all selected cadences will be processed and analyzed. The effects of walking cadences on plantar pressures will be evaluated.

[85c] Normal Cane Cadence

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Purpose—When studying plantar pressure it is recommended to control cadence because the velocity of walking (stride length \times cadence) affects ground reaction forces. Cadence directly influences the anterior-posterior ground reaction force at toe-off, and has a major influence on the observed ground reaction forces in all three orthogonal directions. Thus, when studying the effect of a cane on plantar pressure it would be important to define the cadence studied. The literature, however, does not define what cadence would be appropriate to use for studies with a cane. The purpose of this study was to define the range of normal cane cadence.

Methodology—A standard J cane is being used. It is fitted to the distal crease of the wrist for each subject. We are using insoles each instrumented with seven pressure sensors and a portable microprocessor-based data-

acquisition system for data collection. The sample frequency is 35 samples per second for each sensor. The system is completely battery powered; it is mounted within a 20cm \times 18cm \times 7cm metal box, and weighs 0.8kg. Subjects can carry the portable system in a backpack during ambulation. This system offers the advantages of portability and minimal interference with the subject's natural gait pattern. Timing data is available for every step for over 4 minutes of continuous recording time.

Results—This study is in progress. Ten normal subjects are being studied. Preliminary data shows approximately a 75% slowing in cadence with use of a J cane. Further work is in progress to define the cadence change with ipsilateral unloading versus contralateral unloading and various types of canes.

[85d] Long-Term Studies of Plantar Pressures Under Insensate Foot

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Purpose—The objective of this research is to study the long-term variability of in-shoe plantar pressures.

Methodology—We are using insoles, each instrumented with seven pressure sensors and a portable microprocessor-based data-acquisition system, for data collection. Seven sensors are located under the posterior heel, anterior heel, first metatarsal head, second metatarsal head, fourth metatarsal head, fifth metatarsal head, and the hallux. Three diabetic subjects with insensate feet were included in our study. Their feet were free from ulcers, trauma, and deformities. Plantar pressures under seven locations were recorded during 4 minutes of continuous walking with a total of 41 tests (each consisting of six trials) over a 1-year period (total 11,500 steps). The subjects walked on a 32 m walkway at their free cadences (mean 105 steps/min) both with and without the assistance of a metronome, respectively. An unpaired *t*-test

($p=0.05$) was used for analyzing data consistencies and indicating statistical differences.

Results—The average intertrial consistencies of all tests were found to be 82% in terms of pressure-time integral, 85% in terms of foot-floor contact durations, and 74% in terms of peak plantar pressures. Pressure-time integral analysis showed inter-test consistencies in 50% of sensor sites. The other 50% showed significant inter-test differences; however, no specific pattern of changes was observed during the whole period. There were no significant differences in intertrial pressure consistencies between uncontrolled and controlled cadences.

Recent Publications Resulting from This Research

Pressure Distribution Beneath Sensate and Insensate Feet. Zhu H et al., in Proceedings of the Annual Conference of the IEEE Engineering in Medicine and Biology Society, 11:822-823, 1989.

[86] Assessment of Walking Handicap and Reflex Control of Normal and Pathological Walking

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Sponsor: *Millenium Scholar: Department of Industry and Commerce, Dublin, Ireland; Mater Hospital College for Postgraduate Research, Dublin*

Purpose—The research activity in this Department is directed at human locomotion. There are two main strands: 1) assessment of walking handicap; and, 2) reflex control of normal and pathological walking.

Progress/Methodology—*Assessment of Walking Handicap.* The walking ability of 26 paraplegic patients was assessed by quantifying the patient responses to a questionnaire concerning their level of walking ability in the home and community. Correlational analysis revealed a good relationship between these scores, assignment to categories of functional walking ability by expert clinicians, and certain sections of the Sickness Impact Profile.

Results—The results support the use of six categories of functional walking ability developed by Dr. Jacquelin Perry and her group.

Future Plans/Implications—A scored questionnaire on walking ability in the home and community provides the initial database for a computerized system of assessment of walking handicap suitable as a means of communication of treatment outcome between the medical, rehabilitation, and social services currently being tested in the context of Eureka Project CALIES (i.e., Computer Assisted Locomotion by Implanted Electrostimulation).

Purpose—*Reflex Control of Normal and Pathological Walking.* Our purpose was to investigate changes in the excitability of the monosynaptic reflex during walking in the stroke patient.

Progress/Methodology—The excitability of the monosynaptic reflex was investigated in 10 stroke patients using the Hoffman reflex modified for use in walking. Previous studies demonstrated increased excitability of the monosynaptic pathway from the ankle extensor during stance phase, and decreased excitability during swing of walking in normal healthy man.

Results—The H reflex showed no significant changes in the excitability of the monosynaptic reflex during walking in the hemiplegic patient. This absence of modulation of monosynaptic reflex in the affected ankle extensor of stroke patients is likely to contribute to walking difficulty (e.g., facilitation of unwanted plantar flexion leading to toe stubbing).

Future Plans—We plan to investigate the relationship between impairment of reflex control and walking handicap in stroke patients, and to develop a computerized system of classification of walking handicap as part of a Telemedicine communications system.

Implications—This study will assist in the identification of the contribution of impairment of the monosynaptic reflex to walking handicap in stroke patient.

Recent Publications Resulting from This Research

Classification of Walking Handicap in Paraplegia. Meehan C, Garrett M, in Proceedings of the 5th European Regional Conference of Rehabilitation International, Dublin (in press).

Changes in the Excitability of the Hoffman Reflex During Walking in Hemiplegic Man. Garrett M, Bin Shakoor S, J Physiol, Proceedings of the Physiological Society, Belfast Meeting (in press).

[87] Comparison of the Kinematic and Kinetic Components of Gait in Adult Males with Obesity and in Males of Normal Weight

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Sponsor: *Foundation for Physical Therapy; Sargent College of Allied Health Professions; NeuroMuscular Research Center*

Purpose—The purpose of this study was to compare kinematic parameters at the knee and ankle, and the temporal and displacement factors in males of normal weight, with and without additional load, to those of males who were 40 to 70% overweight. Data were collected using the WATSMART optoelectronic position measurement system, and processed using the TRACK software. Small rigid arrays, instrumented with infrared light-emitting diodes, were attached to the thigh, shank, and foot of each subject. The position information measured by the cameras was then used to calculate the 6 degrees-of-freedom of each one of those links. The data were used to calculate the anatomic joint rotations involved in the process of gait. A voltage-differential

system of foot-switches was used to correlate the joint rotations, and the kinematic events such as heel-strike, foot-flat, and toe-off.

Results—Results of the data analyzed for 5 normal-weight subjects, with and without load, and 5 obese subjects, suggest that a normal-weight loaded subject presents a different pattern of gait than an obese subject. The results of this study will be used to generate a normative biomechanical profile of gait for the overweight population.

A portion of this work was presented at the 64th Annual Meeting of the American Physical Therapy Association in Nashville, TN, in 1989.

[88] Quantification and Display of Musculoskeletal Anatomy

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Patient-specific anatomical data, in a form suitable for mathematical processing, are essential for accurate determination of the mass and inertial properties used in Newton's equation to calculate forces from accelerations (see "Mobility Analysis" project, p. 77), for specializing mathematically expressed, generalized musculoskeletal models to the particular patient's anatomy (see "Musculoskeletal Modelling" project, p. 79), and to provide the surgeon, via computer graphic displays, with realistic and accurate visual information describing the patient's anatomy (see "Computer-Aided Surgical Simulation of Femoral and Tibial Osteotomy" project, p. 59).

defines local tissue density and is converted to mass density for inertial properties and to grey scale to compute visualization displays. MRI image data requires contouring regions of different density (i.e., bone, muscle, etc.), and assigning tissue density values. We have developed software algorithms to automatically extract from CT and MRI data, and store efficiently in computer memory, the geometrical information necessary to generate colorgraphic computer displays of aspects of a patient's anatomy (i.e., the skeletal bones, joints, muscles, muscle insertions and origins, ligament insertions and origins, etc.)

Using such displays, we have demonstrated the ability to perform any conceivable intertrochanteric osteotomy using a three-dimensional (3-D) computer display of a patient's femur, described from actual CT data. Our approach is fundamentally different from that of commercial firms developing similar anatomical display capability (CEMAX, PIXAR, SIEMENS), in that we are

Progress—We have demonstrated the feasibility and practicability of applying computer tomography (CT) or magnetic resonance imaging (MRI) data to automatically calculate the mass, mass center, and inertial tensor of body segments with X-ray tomography. The CT number

interested in "doing surgery" on the display; that is, "cutting" bones and "glueing" them back together. Commercial firms are content to display the intact anatomy as is. Our approach makes very different demands on the organization and display of the database representing the anatomical information. For 3-D display and graphic manipulation of anatomical material, we are employing both the more common "pixel" approach (using a Silicon Graphics Personal IRIS 4D20) and a volumetric "voxel" method (on a Sun 4/280S system equipped with Sun/TRANCEPT image generator). The two methods are complementary. The surface representation method allows fast manipulation of the anatomy, but requires considerable preparation of the contours. The volumetric method requires little preprocessing, but is computationally expensive and requires specialized image processing hardware. The volumetric representation is clearly superior for computation of mass/inertial properties of

patient-specific body segments. The volumetric displays are particularly striking graphically, and effective interactively. Starting with the external appearance of the body, software, using tissue density as control, can "strip off" the skin, then the subcutaneous tissue, followed by muscle, leaving the skeletal structure.

CT-based images of bone suggest higher densities at ligament and tendon insertion sites; thus, noninvasive patient-specific determination of this data for musculoskeletal modelling appears feasible.

Recent Publications Resulting from This Research

Automatic Three-Dimensional Mesh Generation of Skeletal Structures. Levesque S, Masters thesis, Massachusetts Institute of Technology, 1989.

Determination of Body Segment Parameters in Conjunction with Computer-Aided Surgical Simulation. Brown GA, Rowell D, Mann RW, East/West Coast Gait Laboratories Conference, San Diego, 1990.

[89] Mobility Analysis

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Purpose—Quantitative functional assessment of neuromusculoskeletal disorders mandates an ability to acquire precise, accurate, and high data-sample-rates of the kinematics and dynamics of the affected person. Such measurement is imperative to confident evaluation of the individual's movement patterns before and after interventions such as surgery, physical therapy, and application of internal and external prostheses and orthoses. A major effort of the Harvard-MIT REC has been dedicated to what is now recognized as the premier movement analysis extant.

The MIT TRACK[©] (Telemetered Rapid Acquisition and Computation of Kinematics) software complements Selspot or other electro-optical or video cameras to process human movement data. The NEWTON program uses this kinematic data together with forceplate data and body-segment inertial properties to estimate the new forces and moments across the skeletal joints. Unlike other gait analysis systems which place markers on the skin over the putative joint "centers," TRACK is based on segmented analysis treating each body segment (i.e., foot, shank, thigh, pelvis), as a separate entity free to move in three-dimensional (3-D) space. Arrays of

markers located on each segment permit acquiring, following, and recording the 6 degrees-of-freedom of each segment (3 translations and 3 rotations).

Other features of TRACK are:

- A normal and natural milieu for the human subject, minimizing artificial aspects of the experimental environment and the burden on the subject.
- High precision, 3-D kinematic data, with body-segment translations and rotations relative to a laboratory fixed frame of reference, at high data rates relative to the frequency components of human movement, in a form suitable for subsequent dynamic analyses.
- Automaticity—no human intervention in data acquisition and quantization to eliminate human subjectivity and error and to reduce drudgery.
- Real-time processing of kinematic and forceplate data to provide access to kinematic and dynamic results during or immediately after movement.

Progress—The TRACK system is operational at MIT and MGH, at Boston University's NeuroMuscular Center, and at the University of Bologna. Originally coded in FORTRAN and running under VMS on a DEC PDP

11/60, TRACK has been reprogrammed in the "C" language and transferred to a Sun 3 Microcomputer System running in UNIX. TRACK data are now available at over 100 Hz for real-time control of experiments requiring movement input. For observational and comparative purposes TRACK output is displayed as animated limb and body segments, each a four-color six-sided solid assembled into a representation of a person. This visual display, together with graphical information, is presented on a Silicon Graphics Personal IRIS (4D20) at 20 Hz. A version coded for personal computers is offered commercially by OsteoKinetics, Inc., Newton, MA, under copyright license from MIT.

The kinematic quality of TRACK output has inspired careful study of optimal postprocessing of the sampled position data to faithfully retain all movement—significant frequencies while producing trajectory smoothness essential to satisfactory differentiation. Velocity data are necessary for instant helical axis determination to present joint axis trajectories as axode in order to compare kinematic data independent of subject direction of movement and frame of reference. Acceleration data is necessary for dynamic estimates. Even higher order derivatives are necessary to apply differential geometry analyses to quantitatively compare axode trajectories.

Our study of optimal postprocessing has clearly demonstrated the advantage of smoothing over filtering. We have now compared position data acquired with TRACK arrays mounted noninvasively on the skin on body segments with comparable arrays mounted on bone pins into the skeleton *in vivo*. These, in turn, have been compared with the usual practice of other gait laboratories, that of mounting "joint center" markers on the skin over bony prominences at each of the lower extremities.

With fixed position cameras, the viewing volume for accurate data is about 2 m on the side, or one gait cycle. To study stride-by-stride variability and other noncyclical and wider ranging movement patterns, we have developed Large Volume TRACK. The fixed cameras now observe the subject via computer-controlled mirror systems which rotate to keep the light emitting diode (LED) array images aligned to the camera optical axes as the subject moves throughout a much larger viewing volume.

Advancing Large Volume TRACK required developing improved calibration means, both for correcting

inherent nonlinearities in the camera lens and electro-optical transducers, and in relating the positions and orientations of the cameras to each other and to the laboratory frame. The internal camera calibration technique we have developed and demonstrated fully exploits the 12-bit digitization of the analog output of the lateral-effect diodes in the electro-optical cameras. The new external calibration system is clearly superior to both our prior technique of mounting the cameras on an optical bench and to the widely used Direct Linear Transform (DLT) space-frame approach. We use LEDs mounted on a simple planar frame, rotated about a vertical axis by a stepping-motor, so that the plane can first face one camera, sweep out a volume, and then be rotated to face the other. Eliminating the DLT space frame avoids difficult reflections from frame structure between an LED and the camera, yet rotation of the plane simulates a volume. Finally, a new calibration algorithm has been developed which does not require that both cameras simultaneously see the same LED.

Recent Publications Resulting from This Research

- Automatic 6-D.O.F. Kinematic Trajectory Acquisition and Analysis. Antonsson EK, Mann RW, ASME J Dyn Syst Meas Control 111, 1989.
- Biomechanical Analysis of Knee Motion Upon Stair Ascent and Descent. Markovich GD et al., in Proceedings of the 13th Annual Meeting of the American Society of Biomechanics, 116-117, Burlington, VT, 1989.
- Human Analysis Movement—Opto-Electronics, LED Arrays, and Software Produce Rapid, Automatic, and Precise 3-D Position and Orientation Kinematics and Dynamics. Rowell D, Mann RW, SOMA 3(2), 1989.
- Real-Time Analysis and Display of Kinematic Data. Lord PJ, Mann RW, East/West Coast Gait Laboratories Conference, San Diego, 1990.
- Segmental Analysis in Kinesiological Measurements. Ladin Z et al., in Proceedings of the First World Congress of Biomechanics, La Jolla, CA, 1990.
- A Technique for Large Volume Acquisition of Human Kinematics. Mansfield PK, Mann RW, East/West Coast Gait Laboratories Conference, San Diego, 1990.
- Telemetered Rapid Acquisition and Computation of Kinematics: The M.I.T. TRACK Movement Analysis System. Mann RW, East/West Coast Gait Laboratories Conference, San Diego, 1990.
- TRACK: The MIT Movement Analysis System Which Combines Opto-Electronics, LED Arrays, and Software to Produce Rapid, Automatic, and Precise 3-D Position and Orientation Kinematics and Dynamics. Rowell D, Mann RW, in Proceedings of the International Symposium on Gait Analysis State-of-the-Art of Measuring Systems and Their Importance in Prosthetic and Orthotic Technology, Berlin, 1990.

[90] Musculoskeletal Modelling

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Purpose—Musculoskeletal modelling has been a focus in our research for over a decade. The accurate kinematics from TRACK and dynamic calculations using NEWTON make feasible the estimation of the time course and net force levels in each of the redundant set of participating muscles producing a movement pattern. However, to make such models subject-specific, the mathematically expressed models which define the three-dimensional geometry of the skeleton, joints, muscles, and ligaments of the human lower extremity must be adjusted to the parameters specific to the patient (i.e., bone length dimensions, and muscle/tendon origins and insertions). Our computer tomography and magnetic resonance imaging data approach produces the information necessary for such individualization of our musculoskeletal models (see "Quantification and Display of Musculoskeletal Anatomy," p. 76).

Progress—The data from the pressure-instrumented prostheses (see "Rehabilitation Implications of *In Vivo* Hip Pressure Measurements," pp. 291-294), and corroborating evidence from Newman Laboratory amputations prostheses research and the posture and balance studies at the Massachusetts General Hospital's Biomotion Laboratory have made increasingly clear the ubiquity and significance of agonist-antagonist muscle activity (co-contraction) in virtually all postural adjustments and movements. The significance of these findings to gait analysis, the estimation of joint forces and movements, muscular skeletal modelling, and individual muscle force determination using optimization approaches, cannot be underestimated. In a word, all extant studies of the above have been based on, or have yielded, the lower limit of the forces the muscles provide and the joints experience.

Since all such studies start with movement data (i.e., kinematics), they reflect only the net muscle forces which cause the motion, due to the muscle moment at the joint. In co-contraction, muscles opposed (antagonistic) exert balanced forces and therefore, joint forces above these net values. But these balance forces do not contribute to the observed motion.

Results/Implications—Amputation prosthesis research in our laboratory is showing that co-contraction is essential to the control of the impedance or stiffness of the joint, especially when the human interacts with the environment, in the use of tools.

We are developing a new analysis technique to include co-contraction in our optimization analyses which estimates the force-time output of the individual muscles. In such studies, a cost or penalty function (e.g., energy expenditure), is minimized to find those solutions which also satisfy the dynamic constraint equations. Adding a new "stability" cost function requires that the muscle forces, and their aggregate, the joint forces, be adequate to keep the body stable during movement maneuvers.

Recent Publications Resulting from This Research

- Agonist-Antagonist Muscle Co-Contraction: Ubiquitous but Unappreciated. Mann RW, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 57-58, 1990.
- A 3-D In Vivo Knee Model: Relationships Between Geometry, Dynamics, and Kinematics. Fijan RS, Mann RW, ASME Winter Annual Meeting, Symposium on Issues in Modeling and Control of Biomechanical Systems, Dallas, 1990.
- A Three-Dimensional Mathematical Model of the Human Knee Joint. Fijan RS, PhD diss., Massachusetts Institute of Technology, 1990.

[91] Development of a Gait Pathology Expert System

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Sponsor: National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health

Purpose—The goal of this project is to develop a knowledge-based (expert) system which identifies the cause of a patient's gait dysfunction from an analysis of basic gait data. The intent is to assist the clinician by providing the primary and secondary diagnosis, with an explanation of the underlying reasoning process.

Methodology—The approach involves: 1) design and development of an automated Data Analysis Expert System (DA/ES), or preprocessor, which will analyze and evaluate the raw data obtained from instruments and yield judgments relating the specific data set to the parameters of normal walking; 2) design the evaluation of a Gait Pathology Expert System (GP/ES), which uses the outputs from the DA/ES and a gait analysis knowledge base to identify the muscular dysfunction responsible for the observed deviations from normal gait; and, 3) making preliminary plans for establishment of a National Resource Center to disseminate results of this project.

Progress/Results—A system (DA/ES) to delineate automatically the timing and relative intensity of gait electromyographic (EMG) data has been designed and validated with normal and patient data. A normal database has been compiled consisting of EMG data (27 muscles), foot support pattern and gait phases information (104 subjects), and motion (50 subjects) analysis. Software modules defining deviations between the automatically delineated patient data and the normal data bank have been developed. The basic GP/ES has been completed and validated with patient data for ankle gait deviations. "Reference frames" store the knowledge base. A rule-based tree

structure has replaced direct matching of patient frames. The causes of five gait deviations have been related to seven modes of muscle action and foot switch patterns with hip and knee compensating postures included.

Future Plans/Implications—Proposed are means of improving DA/ES sensitivity to pathology. Normal phasing of the two joint muscles will be refined with new data which relate variations in EMG to their other functions. The phasic changes in EMG intensity during a muscle's activity period will be defined. For use of the DA/ES with surface EMG, the effects of different filters and the ability to differentiate the actions of the 21 muscles with surface exposure will be determined. The diagnostic capability of the GP/ES will be extended by incorporating a qualitative physiological mode (QPM).

This will be used when the tree/frame system does not provide a diagnosis. Efficiency of the QPM will be enhanced by an inductive learning module which extracts rules from repeated solutions. Means of handling variability will be developed and inferences will be added to the clinical explanation. Validation with patient records will be ongoing. Outcome will be judged by two external gait experts. An instructional course and commercial availability will disseminate the information.

Recent Publications Resulting from This Research

The Sequence of Extensor Muscle Control in Walking. Perry J, Gronley JK, Bontrager EL, in Proceedings of the 36th Annual Meeting of the Orthotics Research Society, New Orleans, 1990. Computer-Aided EMG Analysis of Gait. Bontrager EL, et al., in Proceedings of the First World Congress on Biomechanics, San Diego, 1990.

[92] Curve Estimation in Motion Analysis

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Sponsor: National Science Foundation

Purpose—Our primary interest in this project is to develop methods to describe gait data in such a way that it can be used for clinical decision-making, and to expand a course of work in which nonparametric

smoothing and the bootstrap are applied to several real-world problems in biomechanics and robotics. This involves developing methods to detect and classify abnormalities.

Progress—This project has advanced in several areas. Much of the work of the past year has been data checking on the gait data for the analyses. This has been completed and errors corrected. Two projects, in modeling how output errors propagate from errors in the input, and work on measuring dynamic robot motion, have advanced. Similar work in the area of robotics may allow for better control strategies or diagnosis of controller problems.

Recent Publications Resulting from This Research

Sensitivity of Cruciate Force to Input Data Error. McGibbon C, Biden E, Sexsmith J, Fifth Annual East Coast Clinical Gait Laboratories Meeting, 1989.

How Many Subjects Do You Need to Define Normal.

Biden E, First Combined East/West Coast Gait Laboratories Conference, 1990.

[93] Assessment of Variability in Human Walking and in Robots

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Sponsor: *Natural Sciences and Engineering Research Council of Canada*

Purpose—The purpose of this project is to expand on existing variability models which are applied to human movement for gait analysis, and to extend the analysis to robot motion.

Progress—During the past year the effects of sample size on the ability to define "normal," and the effect of side-to-side phase shifts have been examined and reported.

Recent Publications Resulting from This Research

A Comparison of Two Classification Methods for Gait Data.

Biden E, Kelly M, in Transactions of the Canadian Orthopaedic Research Society, 1989.

Sensitivity of Cruciate Force to Input Data Error. McGibbon C, Biden E, Sexsmith J, Fifth Annual East Coast Clinical Gait Laboratories Meeting, 1989.

Side to Side Symmetry in Knee Flexion. Biden E, Wyatt M, Sutherland D, Fifth Annual East Coast Clinical Gait Laboratories Meeting, 1989.

Side to Side Symmetry in Normal Knee Flexion. Biden E, Wyatt M, Sutherland D, presented at the Combined Meeting of The Canadian Ortho Research Society and Canadian Orthopaedic Association, 1990.

Transverse Acceleration, Velocity and Displacement in Robots in Straight Line Motion. Boudreau R, Biden E, presented at the 9th Canadian CIM/D, Toronto, 1990.

[94] Clinical Assessment of Hemiplegic Gait Following Stroke: A Pilot Study

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Sponsor: *Scottish Home and Health Department*

Purpose—Our purpose was to develop and pilot-test a gait assessment form for recording the visual observations of clinicians on patients with hemiplegic gait following stroke.

Methodology—A detailed gait analysis form is being developed in conjunction with physiotherapists at The Queen's College, Glasgow, and various Glasgow hospitals. Concurrently, stroke patients are being filmed walking along an instrumented walkway. Six patients will be filmed at two stages in their recovery, using antero-posterior and lateral cameras mixed to give a split-screen

film. These films will then be watched by three experienced stroke rehabilitation physiotherapists, who will use the form to rate the patients' gait. Validity of the form will be tested by comparing the completed forms to the walkway data, which gives information on speed and symmetry (in particular, speed, single-support symmetry, and step-length symmetry, although other parameters available from the walkway will be used in the final analysis if necessary). Reliability of the form will be tested by having the same rater score the same video on three different occasions (intra-rater reliability), and by having different raters score the same video (inter-rater

reliability). Correlations will be examined between the subjective and the objective data.

Progress—The instrumented walkway and cameras have been set up in the Rehabilitation Department at the Southern General Hospital, Glasgow. Five patients have been filmed at various stages in their recovery, but it has been found that some of the data collection sessions will have to be discarded as the patients' gait was too poor to allow the walkway to collect valid data. It has also been noted that there tends to be a learning effect on the patients as they get used to the unfamiliar walkway. The first trial for any patient is, therefore, discarded, and the data collection proper starts on the second trial which is held the day after the first trial, where possible.

We will be starting the rater trials shortly as the form is in the final stages of development, and enough patient videos have been collected to make up suitable tapes.

Results/Implications—So far, the results are confined to the walkway data. These appear to confirm the usefulness of speed and symmetry as measures of recovery, and the walkway has proven to be sensitive enough to record very minor changes in gait. In particular, it has shown that as patients improve, not only do their speed and symmetry improve, but the variability of these parameters as measured by the standard deviation decreases (i.e., they become more consistent). However, this observation will have to be confirmed in a later study.

[95] Mechanics of Ankle-Foot Orthoses

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Sponsor: *University of Akron*

Purpose—Excess rotations at the ankle-foot complex present a major problem in the comprehensive rehabilitation of certain stroke patients with upper and lower motor lesions. These patients have uncontrolled muscle activity which may develop into the "drop-foot" problem. Abnormal rotations also occur in the case of certain ligament injuries. Ankle-foot orthoses are generally prescribed to mitigate this problem. However, these orthoses have not been evaluated from a biomechanical viewpoint. The purpose of the present investigation is to study the biomechanics of ankle-foot orthoses.

Progress—We have developed two-dimensional finite element models of the ankle-foot-orthosis complex and studied various static and dynamic loading conditions. We compared stress and deformation patterns of the normal foot with those fitted with an orthosis.

In addition, we experimentally examined the strains developed in the orthosis in a walking cycle. Strain gauges were attached to polypropylene orthoses. The orthoses were fitted to normal test subjects and the strains were recorded during the gait cycle. The orthosis was held in place with a strap anterior to the calf and a shoe which held the foot in the lower section. Principal strains were determined from three element Rosett gauges with assumed values for the material properties.

Preliminary Results—Peak stresses determined from both static and dynamic finite element models were similar in magnitude. Experimental results with strain gauges were consistent with the results of finite element model simulation. Slight geometric modifications of the orthosis were made to eliminate stresses at undesirable points. These design modifications allow functional plantar flexion, reduce instability at the subtalar joint, and facilitate heel-to-toe gait pattern.

Future Plans/Implications—While the present simple two-dimensional analyses demonstrate the feasibility of using finite element models for redesigning the ankle-foot orthoses, further examination of dynamic conditions and more complex three-dimensional (3-D) dynamic finite element calculations are needed to be able to predict the total response of the ankle-foot orthosis system.

We are developing 3-D finite element models of ankle-foot-orthosis systems. In addition, we propose to test-fit the orthoses to human subjects and examine the effect of these orthoses on knee, ankle, and subtalar joints. Also, we plan to verify the results of the 3-D finite element model with experimental stress analysis of these orthoses. This would provide a comprehensive biomechanical understanding of the ankle-foot-orthosis systems.

[96] Development of a Posture Sensor and Evaluation System for Use in Gait Training of the Locomotion Disabled

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Sponsor: *None listed*

Purpose—In the locomotion-disabled person, such as paraplegic or hemiplegic patients with balance deficits, information about pelvic inclination is most useful from the rehabilitation point of view. In the present study, pelvic inclination and its time derivative in the sagittal and frontal plane, as well as in the transversal plane during walking, are measured by the use of an inclinometer based on the gyroscope principle. This posture sensor system is used to evaluate gait and its improvement, if any, through rehabilitation.

Methodology—Inclinometer and angular rate sensors are put on the pelvis by belts for measurement of absolute angular displacement of the pelvis in sagittal and frontal planes, and measurement of angular rate in the transversal plane, respectively. Foot-switch sensors on the soles of the patient's shoes are used to detect plantar contact instants. The information is acquired and treated on-line in real-time by a 16-bit personal microcomputer via A/D converter.

Progress—Several software programs have been developed for measurement, data processing, and graphic presentation on-screen, and then tested on the normal subjects' walks as well as on patients having hip-joint disorders. Some criteria softwares have been developed to evaluate rehabilitation exercise.

Preliminary Results—Preliminary experiments indicate that a graphic presentation shows basic characteristics of each patient's gait: for example, the walk of women who have osteoarthritis at the hip joint before and after surgical operation. Data acquired from normal subjects and patients have been characterized by the proposed check points with regard to the waveform. It has been shown that these points can reveal the differences between them. Six features of a set of angular patterns were pointed out, and some were found to be invariant, while the rest vary, reflecting the degree of the disorder. Preliminary experimental results show the effectiveness of this system in the quantitative gait analysis, and evaluation of the patient's progress in rehabilitation exercise.

Future Plans/Implications—We expect to develop an expert system of analysis and evaluation of gait of each patient for use in a rehabilitation program, and for evaluation of its effects. This system is simple, compact, and especially suitable for clinical applications.

Recent Publications Resulting from This Research

Development of Measuring and Evaluating System of Three-Dimensional Angular Displacement of Pelvis During Walking. Miyamoto H, Yamazaki T, Kitame S, Ishida T, in Proceedings of the 11th Biomechanism Conference (SOBIM Japan), 153-156, 1990 (in Japanese).

C. Other

[97] Nuclear Magnetic Resonance (NMR), Biochemical, and Biomechanical Studies of the Human Foot Pad

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A466-RA)*

Purpose—Our preliminary studies with human foot pads indicate that the human foot pad tissue consists mostly of triglycerides and that their component fatty acids are

more unsaturated than those of other adipose tissue triglycerides found in the body. Increased unsaturation results in a decreased viscosity of the triglycerides.

Biomechanical formulation predicts that decreased viscosity improves the shock absorption properties of the foot pads.

Our research goals are to: 1) develop a noninvasive method permitting the quantitation of the amount of lipid in the human heel pad; 2) develop an apparatus to test the biomechanical properties of the human heel pad *in vivo* in an attempt to correlate the composition data with biomechanical properties; and, 3) continue the biochemical studies on the composition of the fibro-fatty tissues of "normal" and abnormal human foot pads obtained at surgery. It is hoped that this information will lead to prevention of some human foot disease and improved treatment of such disease.

Results—The continued biochemical studies on "normal" human foot pads have confirmed in 60 human foot pads that our preliminary observations on the unsaturation of the fatty acids were correct and have provided us with statistically significant results. We are now collecting foot pads from abnormal conditions. All the nonlipid residues obtained from the foot pads have been saved and preliminary evidence (hydroxyproline analyses) indicate that most of this residue is collagen. We are currently setting up a procedure that will allow us to type these collagens.

The procedures to quantitate the amount of lipid in the human heel pad by determining lipid-to-water ratios by nuclear magnetic resonance (NMR) have been improved, which will facilitate the examination of addi-

tional patients by this noninvasive procedure. The diabetic females examined (n=4) had a significantly lower lipid-to-water ratio than normal females (n=12) at the $P=0.01$ level. However, the differences between normal and diabetic males were not significant. These studies will be expanded in order to improve the statistical significance and to examine the surprising differences between sexes since it is now commonly believed that no sex difference exists in diabetes mellitus.

The apparatus for noninvasively evaluating the viscoelastic properties of *in vivo* human heel pads is operative. All the software problems have been resolved and we are currently optimizing all parameters on volunteers' and cadaver heel pads. We expect to examine the same subjects on the same day by using NMR to obtain the lipid-to-water ratio, and using the viscoelastic properties of the heel pads with this device, to determine if a correlation exists between these two parameters. Of special interest will be the determination of the viscoelastic properties of the heel pads of those diabetic females that have low lipid-to-water ratios as determined by NMR.

Future Plans—Apparatus and procedures for measuring the mechanical properties of human heel pads *in vitro* and *in vivo* are now complete. We plan to investigate mechanical heel pad parameters, including viscoelasticity, to compare them to NMR properties concurrently, and to biomechanical parameters as established for similar cases of individuals during the earlier part of the study.

[98] An Investigation of the Relationship of Postural Sway and Endurance in Sitting

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Sponsor: *Easter Seal Research Institute of Ontario*

Purpose—This study focused upon the evaluation of postural sway in sitting of 50 normal and 16 neurologically impaired children. A postural tracking system was used to monitor stability (trunk sway) during static sitting on a conventional horizontal seat base, and to determine the effects of a forward-inclined seat base on sway of children with cerebral palsy, and children with traumatic head injury. The objectives of this study were twofold: 1) to examine the developmental nature of sway in static sitting balance of normal children, so that these data could be used as benchmarks for evaluating sway in disabled children; and, 2) to examine the effects of horizontal

(0 degree) and forwardly-inclined (10 degree) seats on stability of neurologically impaired children.

Methodology/Results—Sitting stability was defined as the standard deviation of trunk movement along three axes. A significant linear trend between sitting stability and age in normal children was observed. Sitting stability was poorer in children with cerebral palsy than in normal children, while no difference was observed between the normal and head-injured children. When the seat angle was tilted 10 degrees anteriorly, there was no difference in trunk sway for either group.

[99] Biomechanical Measurements for Quantitative Assessment and Diagnosis of Dysphagia

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Sponsor: *Edwin Shaw Hospital Foundation*

Purpose—Dysphagia is a swallowing disorder resulting from neurological impairment. It presents a major problem in the comprehensive rehabilitation of patients with stroke and other head injuries. Further, dysphagia often leads to several clinical problems such as aspiration, dehydration, and inadequate nutrition. Identification of the patient at-risk of aspiration is important from a clinical standpoint.

The swallowing process can be divided into three distinctive phases: oral, pharyngeal, and esophageal phase. We are developing procedures for quantitative assessment and diagnosis of dysphagia involving the oral and pharyngeal phases.

Progress/Methodology—We have identified and developed techniques to measure several biomechanical parameters which aid in the quantitative assessment of the oral musculature in dysphagia. These parameters include: 1) lip closure pressure; 2) lip interface shear force; 3) tongue thrust in forward, backward, and two lateral directions; and, 4) swallow pressure.

For the quantification of the pharyngeal phase, two ultra-miniature accelerometers were placed on the outside of the throat. In addition, the swallow pressure was monitored with a catheter placed at the base of the tongue and connected to a pressure transducer. Normal subjects and dysphagic patients were measured for acceleration and swallow pressure simultaneously. A correlation was also made between the biomechanical measurements and videofluorography examination.

Preliminary Results—We found statistically significant differences in the above parameters measured in normal and dysphagia patients. In current clinical practice, the strength of the oral musculature is assessed using tongue depressors and lollipops. The biomechanical parameters devised in the present investigation can aid the physician to objectively assess the recovery of the dysphagic patient.

Swallowing in normal individuals gave rise to a characteristic acceleration pattern which could be well-reproduced. The amplitude of acceleration varied from

1 to 2 g. There was no time lag between the appearance of the pressure wave and the appearance of the acceleration wave characteristic of swallowing.

By contrast, in 35 dysphagic patients, the characteristic acceleration pattern was either absent or significantly delayed. The amplitude of acceleration varied from 0 to 0.5 g. In those patients who could trigger a swallow, we found significant lag times between the acceleration and pressure waveforms. Additionally, we measured the biomechanical parameters in several patients upon admission, and after 3 weeks of thermal exercise therapy. We found significant improvements in the acceleration amplitude and pattern after the 3-week therapy. We found similar improvements in oral biomechanical parameters (tongue thrust, lip pressure, etc.), after 3 weeks of oromotor exercises.

We have made biomechanical measurements (BM) of the oral and pharyngeal phases within 7 days of videofluorography examination (VFE) in 36 patients. Both results were independently classified into three categories of risk for aspiration. In 21 cases, there was a complete agreement between BM and VFE. In 11 cases, the BM overestimated the risk by one category, and in 4 cases, underestimated the risk by one category. Wilcoxon, and paired *t*-test did not indicate statistical difference between the two methods.

Future Plans/Implications—The biomechanical parameters identified and the measurement techniques developed in this study can be used for quantitative evaluation of the patient and for patient training to speed up the recovery process. Acceleration, when measured simultaneously with the swallow pressure measurement gives a quantitative picture of the coordination of the swallowing mechanism and can be used in the diagnosis of dysphagia.

In current rehabilitation practice, the pharyngeal phase and coordination are assessed using videofluoroscopy (radiography) which is often very expensive. Our results on the dysphagia patients correlated well with the VFE. However, a study on a large number of patients is necessary.

We are currently in the process of developing and testing instrumentation for biofeedback training for oral dysphagia by giving a visual feedback of the biomechanical measurements. Our hypothesis is that the biofeedback will accelerate the recovery process. Also, the acceleration patterns have to be evaluated in the frequency domain to identify the critical frequencies.

Recent Publications Resulting from This Research

Biomechanical Measurements to Characterize the Oral Phase of Dysphagia Patient. Reddy NP et al., IEEE Trans Biomed Eng 37:392-397, 1990.

Clinical Correlation of the Biomechanical Measurements of the Dysphagic Patient. Canilang EP et al., American Congress of Rehabilitation Medicine Conference, Phoenix, AZ, 1990.

III. Functional Assessment

For additional information on topics related to this category see the following Progress Reports: [86], [155], [181].

[100] C SCAT: A Method for Differential Diagnosis of Tremors Based on Their Response to Mechanical Loads

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Sponsor: VA Rehabilitation Research and Development Service (Project #F482-RA)

Purpose—This research and development project is meant to test the idea that more definitive distinctions can be made among types of pathological tremor by observing the variation of objective tremor characteristics with applied mechanical loads. This hypothesis is based on earlier work in this group and elsewhere, in which sensitivity, or stability of frequency-domain tremor descriptions to added masses, springs, and dampers were used as the basis for investigating tremor mechanisms. C SCAT (Computer-Based System for Clinical Assessment of Tremor) is meant as a prototype instrument for use by neurologists to diagnose movement disorders in a way which will offer more reliable prediction of the effect of drugs and obviate trial-and-error prescription.

Progress/Methodology—The first C SCAT unit has been completed. It is a one-degree-of-freedom manipulandum based on a brushless dc motor digitally controlled to simulate variable amounts of added mass, damping, and elastic resistance. The entire device is mounted for clinical convenience on a cart which provides the necessary sturdy base and lockable casters. The host computer is mounted on the bottom shelf of the cart with the clinician interface monitor on top. A system of adjustable fixtures, limb cuffs, and supports makes it possible to test a patient's left or right arm in wrist extension/flexion, forearm supination/pronation, and elbow extension/flexion.

A patient being tested with C SCAT is asked to perform a simple tracking task presented by means of successive illumination of LEDs arranged in an arc immediately adjacent to his/her limb segment when it is secured in the device. The clinician conducting the test interacts with it through a friendly interface based on a keyboard and menu displays on a color monitor. An extremely detailed database management system has been built-in to facilitate collection and study of expected experimental evaluation data.

Future Plans/Implications—Experimental evaluation has begun at the Brockton/West Roxbury VA Medical Center. Clinical reactions as well as objective data will be collected. The primary task will be to determine if our hypothesis is correct that differences in tremor mechanism which determine drug response can be detected with a test protocol of practical length. The long-term goal will be to correlate tremor profiles generated with C SCAT to drug response for a large group of subjects.

Recent Publications Resulting from This Research

- Design of Patient Interface and Assessment Manager for Computer-Based Tremor Characterization System. Brongo D, Masters thesis, MIT, 1990.
- An Impedance Simulator for the Assessment and Diagnosis of Human Limb Tremor. Loney T, Masters thesis, MIT, 1990.

[101] Psychomotor Test to Evaluate Hand Sensory Substitution Devices: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A984-PA)

Purpose—The purpose of this study was to develop a psychomotor test for evaluating motor performance and function of patients before and after being fitted with sensory substitution devices. A pinch force psychomotor task was constructed with associated apparatus. Test reliability and sensitivity of a psychomotor test paradigm for studying pinch force control was performed using normal subjects.

Methodology—An isometric strain gauge pinch dynamometer was designed, constructed, and interfaced to a microcomputer. The dynamometer was independent of point-of-application, permitting convenient orientation against the fingers. The rapid contract and release task required exertion against the dynamometer at or above a minimum predetermined exertion level as rapidly as possible, using the thumb and index finger. A pointer on the oscilloscope discretely jumped a fixed distance and a chime sounded simultaneously every time the required force level was achieved. The exertion was then released as quickly as possible, and the release had to be less than a predetermined lower force level. After the lower force level was reached, the pointer on the oscilloscope discretely returned to the original position, and another chime sounded. The effect of required force level, intra-subject hand differences, and test-retest were studied using a full factorial repeated measures experimental design.

The dynamometer was calibrated by suspending weights from its handle in the plane of greatest sensitivity. Software was developed for controlling the test apparatus and administering the pinch force psychomotor test. A squared Plexiglas™ box was built to cover the base of the dynamometer, and also to serve as a rest surface for the subject's hand when using the dynamometer. A strength test was administered to every subject prior to performing the psychomotor tasks for establishing appropriate

force levels for each hand. A 3-minute rest period was provided between exertions for preventing fatigue. The strength test was repeated twice for each hand, and the greatest force level achieved was taken as the strength. The required force levels selected in the study were 5%, 20%, 35%, and 50% of the subject's maximal voluntary contraction (MVC). Subjects performed eight counterbalanced experiment conditions, namely, two hands by four required force levels, continuously. Performance measures included reaction time, time-to-peak force, peak force, and over-grip force.

Results/Implications—A pinch force psychomotor test has been successfully developed and constructed. We have measured performance of normal individuals to provide an indication as to whether the task proposed is sensitive to force control effects associated with the insensate hand and other sensory-motor disabilities. Preliminary studies indicated that force has an important effect on pinch rate. An experiment was performed to study the reliability of this test and to establish normal ranges. These preliminary studies indicated force requirement has an important effect on pinch rate. The average reaction rate of subjects was from 2.28 to 7.00 times/sec at 5% MVC, from 1.84 to 5.00 times/sec at 20% MVC, from 1.40 to 4.40 times/sec at 35% MVC, and from 1.20 to 3.56 times/sec at 50% MVC.

The original concept has proven feasible and a pinch force psychomotor test has been developed and tested. It is now available for quantitative testing of hand sensory substitution devices, and thus could form the basis of a project on development of a sensory substitution system for the hand. Another application of this work also became apparent during its development; it could potentially form the basis of a new project on quantitative testing of hand function in the spinal cord injured individual before and after upper extremity tendon transfers.

[102] Rehabilitation Efficacy for Brain and Spinal Injury

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Sponsor: *Centers for Disease Control*

Purpose—The main objective of this project is to determine the reliability, validity, and scaling properties of the Functional Independence Measure (FIM), and the Modified Barthel Index (MBI), two functional assessment measures that have broad utility and general acceptance in rehabilitation medicine.

Progress/Methodology—Each of 10 hospitals are collecting type and duration of therapies received by 15 traumatic brain injury (TBI), and 15 spinal cord injury (SCI) patients. FIM scores and the duration of various

nursing care and education activities over a 24-hour period near the beginning and toward discharge of rehabilitation are also being collected.

Implications—Establishing a valid measure of disability and handicap will better enable clinicians and researchers to plan cost-effective treatment, allow for increased effectiveness and efficiency of care, enhance prediction of rehabilitation outcomes, and to examine the relationship between burden of care imposed on nursing staff and FIM scores.

[103] Portable Microprocessor-Based Heart Rate Processor

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Sponsor: *Hugh MacMillan Rehabilitation Centre*

Purpose—This project is an exploratory study into the possibility of using heart rate as an objective indicator of arousal states (especially states of excitement and enthusiasm, or lack of such states) in severely multiply disabled children. The goals of this study are the application and evaluation of a newly developed portable heart rate monitor and data processing algorithm, and the exploration of heart rate data as an indicator of the effect of sensory stimulation interventions with children who are nonspeaking and severely motorically impaired.

Methodology—A portable unit that measures and stores the interval between ventricular contractions (R-to-R interval) was developed. Data collected by the "beat box" can be downloaded to a MS/DOS-compatible computer.

A total of 30 minutes worth of data can be collected before downloading.

A prototype of the device is currently being field-tested with students of the Hugh MacMillan Centre School. Three children from the Sensory Stimulation class will be invited to participate.

The procedure will be as follows: 1) 5 minutes of rest in low illumination condition; 2) 5 minutes of rhythmic music; 3) 5 minutes of rest in low illumination condition; 4) 5 minutes of toy activation; 5) 5 minutes of rest in low illumination condition; and, 6) 5 minutes of rhythmic music and full illumination.

It is hypothesized that the heart rate for the activity periods will be noticeably different (higher) than that for the rest periods.

[104] Determination of Ankle Range of Motion Using OMNITRACK

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Sponsor: *Hugh MacMillan Rehabilitation Centre*

Purpose—The objective of this pilot study is to develop a system that automatically records ankle position while the foot is moved through its range by the clinician.

Patients being fitted with ankle-foot orthoses (AFOs) are required to have a range of motion about the ankle such that they can be placed in a neutral position. Those with contractures, for instance, may be impossible to place in a neutral position, and are therefore unsuitable candidates for AFOs. Presently, the clinician physically manipulates the foot and ankle and makes a subjective opinion about bracing.

Methodology—OMNITRACK is a device that was developed in the Electronics Programme for the quantification of posture. The hardware consists of a 3-degree-of-freedom potentiometer-based position sensor and a data acquisition card for the IBM-PC. With this hardware, the position of the end of the sensor, with respect to the sensor's base, can be calculated in three dimensions. The hardware was enhanced with the addition of a platform on the end of the sensor. The platform was attached through three additional potentiometers, giving the sensor a total of 6-degrees-of-freedom. With this addi-

tion, it becomes possible to use OMNITRACK to measure the position and orientation of the platform with respect to the sensor base.

Analysis of the system is very similar to the forward kinematics problem in robotic arms. A frame of reference is assigned to each potentiometer, and the Denavit-Hartenberg convention is used to define the relationships between frames. It then becomes possible to determine the position and orientation of the frame of reference of the platform with respect to the base.

The shank is held upright with Velcro™ straps attached to a fixed frame. The platform is placed on the bottom of the foot. The clinician moves the foot through its range of motion and the platform moves with it. By calculating the orientation of the platform, it is possible to determine plantarflexion/dorsiflexion, inversion/eversion and internal/external rotation at each instant.

Results/Implications—The system is able to automatically record ankle range of motion. Further design work is required to minimize the effect of twisting of the bones of the foot relative to the ankle joint, which reduces precision of the inversion-eversion measure of the ankle.

[105] ELITE: A Fully Automatic 3-D System for Movement Assessment

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Sponsor: *Italian Ministry for University and Scientific Research, Italian Research Council*

Purpose—The purpose of the ELITE project is the development of a fully automatic, unobtrusive movement analyzer to be used for routine work in clinical evaluation, diagnosis, therapy and prostheses assessment, and for research applications in neurology and orthopedics.

Methodology—*System overview.* The system is based on optoelectronic noncontact means (TV cameras), and is divided into two levels of intelligence devoted to image-processing, and high-level data processing.

First level. The first level processes in real-time the images taken by two or more CCD/TV cameras leading

to the two-dimensional (2-D) coordinates of small lightweight passive markers placed on the subject's anatomical landmarks. Because a special shape recognition algorithm is used for their detection, high resolution is attained by using small markers. The algorithm is based on a hardware-implemented, real-time bidimensional cross-correlation between the incoming TV image, and a reference kernel which gives high correlation values only for marker-shaped objects. The computation of the center of mass of the cross-correlation values on all the pixels belonging to one marker leads to an increase in the 2-D resolution to 1/65000 of the field.

Second level. The second level is implemented on an AT/IBM-compatible computer (80286/386/486 microprocessors). It provides for distortion corrections, matching between markers, coordinates, body landmarks, three-dimensional (3-D) coordinates, reconstruction, and other further processing. Matching with the body landmarks is a problem that always arises when passive, noncoded markers are used. It has been solved by combining a dynamic tracking procedure with a knowledge-based model of the movement under analysis. This approach has led to a fast, automatic algorithm suitable for routine applications. The 3-D coordinates of the markers are computed by an iterative least-squares algorithm based on the linearization of the colinearity equations. Further processing includes the data filtering and derivatives assessment. This problem has also been solved with a new technique using AR signal modeling. The procedure is fully automatic and very fast. Other processing includes force platform data analysis, body modeling, and graphic representations.

System performances. The system can work with very small markers with respect to the field of view (FOV) (plastic hemispheres of 0.8 cm of diameter on a 3 m FOV), and is very flexible with respect to the calibration volume. Analyses on lip movement involving a 30cm-sided cube have been done, as well as full body double-sided analyses with 5 meters of FOV; obviously the marker dimensions and lenses vary accordingly. The use of reflective paper coating markers, of stroboscopic solid-state infrared lighting, of TV cameras electronically shuttered (1 ms), and of the shape recognition hardware

allows the operation of the system in any environment, even outdoors, allowing for maximum freedom in the experimental set-up. The 3-D calibration of the working volume is easily performed in less than 5 minutes by using a control object carrying a grid of markers. The accuracy obtained on the 3-D coordinates is one part on 3,000 of the FOV, and is sufficient for the major part of the analyses related to the rehabilitation field, considering the high sampling rate (100 Hz). The derivative assessment algorithm has shown a very good accuracy on the third derivative also and, compared with other techniques, has given similar or better results, but with a dramatically lower time consumption and without requiring any *a priori* information on the processed signal.

Recent Publications Resulting from This Research

- Automatic Analysis of Lips and Jaw Kinematics in VCV Sequences. Magno Caldognetto E et al., in Proceedings of Eurospeech 89, J.P. Tubach, J.J. Mariani (Eds.), 453-456, 1989.
- Hierarchical Approach to 3D Movement Analysis. Ferrigno G, SPIE Proceedings, 1356:2-7, 1990.
- Pattern Recognition in 3-D Human Motion Analysis. Ferrigno G, Borghese NA, Pedotti A, ISPRS J Photogram Remote Sensing, 45:227-246, 1990.
- A Technique for the Evaluation of Derivatives from Noisy Biomechanical Data by a Model-Based Bandwidth-Selection Procedure. D'Amico M, Ferrigno G, Med Biol Eng Comput 28:407-415, 1990.
- An Algorithm for 3D Automatic Movement Analysis by Means of Standard TV Cameras. Borghese NA, Ferrigno G, IEEE Trans Biomed Eng (in press).
- Comparing Differentiating Procedures for Kinematic Data. D'Amico M, Ferrigno G, Proceedings of VIII Isek, Baltimore (in press).

[106] AUSCAN System: An Optoelectronic Analyzer of Posture

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Sponsor: Italian Ministry for University and Scientific Research, Italian National Research Council

Purpose—The purpose of this research concerns the development and clinical application of a new automatic system, named AUSCAN, for nonionizing three-dimensional (3-D) measurement and analysis of kinematic and dynamic variables associated with human posture.

Methodology—The AUSCAN system is a new automatic TV-based analyzer of the 3-D variables of posture. Depending on the type of postural test to be carried out, a number of small reflective hemispheres are placed on the patient's body to mark the most proper anatomical

repair points. For example, when studying scoliosis in orthostatic or dynamic conditions (i.e., during bending or stepping), the markers are located on: zygomatic bones, mentum, acromions, sterno-clavicular joints, apophysis of sternum, anterior superior iliac spines, posterior superior iliac spines, knee joints, heels, and spinous processes from C7 down to S3 every second vertebra. After that, the patient is asked to stand on a suitable forceplate which allows, during the whole test, the reconstruction of the spatial-temporal evolution of the ground reaction force. At the same time, two pairs of

CCD cameras work simultaneously to pick up both the front and back view of the patient on the forceplate. Both the video and the forceplate signals join into the hardware kernel of the AUSCAN system where they are preprocessed. The video signals, after suitable conditioning, are sequentially sent to a specially developed architecture (FPSR) for parallel computation. The FPSR is fed with a video image every 10 ms, thus scanning the four cameras in 40 ms. The FPSR main roles are the recognition, inside the original images generated by the cameras, of only the markers placed on the subject, and the computation of their coordinates. The algorithm which the FPSR uses for recognition of markers is a hardware implemented bidimensional cross-correlation function. The particular architecture of the FPSR allows the recognition of any number of passive (reflective) markers present in every single image from any complex environment. A personal computer (where the obtained numerical data has been entered), performs the final data processing, storage, and representation of the results. The AUSCAN system's basic accuracy, originally of just one part over 256 the field of view, is now largely improved by employing a special software algorithm for the estimation of the true center of each marker in space. Such an algorithm leads to an experimentally proved final accuracy of better than 1/3500 the field of view (i.e., an accuracy much better than 1 mm in case of

using a field of view more than adequate for total body analysis).

Results—The primary application of this system has been the analysis of curvatures and rotations of the rachis in normals and scoliotic patients. Preliminary results have pointed out interesting information about the variability of data in normal subjects and, moreover, the effects induced on the patients' spinal deformity by different therapies (e.g., electrical stimulation, braces, surgical intervention, etc.).

Future Plans—The use of the AUSCAN system will continue by following the scoliotic patients' recovery, and by also taking into account further cases in the area of neurological disorders.

Recent Publications Resulting from This Research

The AUSCAN System in the Analysis of Posture. Sibilla P, Pedotti A, Santambrogio GC, in *Proceedings of the IRMA 90, Madrid, Spain* (in press).

Frequency Content of Bending Test Kinematics: A Study to Determine the Optimal Data Filtering. D'Amico M, Ferrigno G, Santambrogio GC, in *Surface Topography and Spinal Deformity VI* (in press).

Three Dimensional Analysis of Posture. Pedotti A, Santambrogio GC, Sacerdoti CG, in *Proceedings of the XVIIth Meeting on Vertigo, Nausea, Tinnitus and Hypoacusia Due to Head and Neck Trauma, Bad Kissingen, West Germany* (in press).

[107] Rating Scale Analysis of Functional Assessment Measures

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose/Methodology—The main objective of this project is to determine the reliability, validity, and scaling properties of the Functional Independence Measure (FIM), and the Modified Barthel Index (MBI), two functional assessment measures that have broad utility and general acceptance in rehabilitation medicine.

Rasch Analysis will be used to examine these properties in 13 impairment groups from data collected by the Uniform Data System for Medical Rehabilitation. The need for adequate measurement of disability is apparent

both in patient care and clinical research for determining compensation, predicting prognosis, planning placement, estimating care requirements, choosing types of specific care, and indicating changes in status.

The objectives of this study are to: 1) assess the utility of Rasch analyses in scaling the FIM and MBI as measures of burden of care, or severity of disability; and, 2) examine change of functional status from admission to discharge, and discharge to follow-up, with scaled scores from the FIM and MBI.

[108] Spherical Coordinate Virtual Environment for Limb-Loading Experiments

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Sponsor: *National Institute on Disability and Rehabilitation Research; Burke Rehabilitation Center*

Purpose—This system was built as an experimental facility for conducting experiments on human motor control; in particular, for research on disabling tremor. It is essentially a 2-degree-of-freedom spherical coordinate robot controlled via digitally-supervised analog loops to behave as a virtual environment. In addition to combinations of inertia, damping, and elasticity, it can simulate detents, rigid walls, and other physical elements. It can also introduce force perturbations. It is based on two brush-type DC servomotors driven by pulse-width-modulated amplifiers. Direct coupling between the device handle and the motor shafts is accomplished by a unique gimbal linkage. For tremor research, the system permits limb-loading as a system identification technique, that is, as a means of modeling tremorogenic mechanisms from their response to changes in apparent limb impedance.

Progress—The system has been subjected to extensive tests to fully characterize it. The efficacy of the redundant

safety mechanisms has been confirmed. Early experimental trials have demonstrated the ability to alter a subject's tremor in frequency and amplitude by elastic loading.

Future Plans/Implications—A protocol has been designed to apply the manipulandum to study of "tremor coordination" (i.e., the relationship between tremors in different degrees of freedom of the same limb). This scheme will involve successive splinting of different degrees of freedom of subjects' arms to separate the contributions of individual joints, followed by collection of data on unsplinted movement.

Recent Publications Resulting from This Research

A High Performance Two Degree-of Freedom Kinesthetic Interface. Adelstein B, Engineering Foundation Conference, Santa Barbara, 1990.

[109] Development of Improved Seating Assessment Review Procedures

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Sponsor: *Scottish Home and Health Department, Chief Scientist's Office*

Purpose—This is a preliminary project intended to develop methods and equipment for quantifying the effects of sitting postures. These are to be incorporated into routine assessment and review procedures for seating. The feasibility of using these procedures is to be determined on a preliminary basis.

Methodology—The following seating characteristics are to be quantified as described below: 1) muscle tone: monitored by EMG instrumentation already developed at this Centre; 2) joint angle: flexible goniometers will measure joint angles; 3) interface pressure: monitored by pressure transducers using either electropneumatic or

electrohydraulic techniques; and, 4) spinal shape: measured indirectly by Oxford Metrics ISIS system.

The above measurements are to be made on a sample of seating patients seen at the Centre, and the results incorporated into the routine patient assessment procedures on the basis of a feasibility trial.

Progress—Funding has been approved for this project which commenced in November 1990.

Future Plans—Depending upon the outcome of this feasibility study, an extended series of trials using these techniques will be conducted to monitor the long-term effects of seating provision.

[110] Objective Functional Assessment and Rehabilitation of Low Back Disability

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Sponsor: *Scottish Home and Health Department; The MacTaggart Trust*

Purpose—Our purpose is: 1) to develop and analyze a model of low back disability which relates physical deconditioning to psychological distress and illness behavior; and, 2) to test that model in the clinical reconditioning and rehabilitation of British patients with low back disability.

Progress/Methodology—The main objective of the first half of this project was to test and standardize the Cybex Isokinetic Back Assessment System for the objective functional assessment of patients with low back pain. This data collection was completed within the planned 18 months. Complete isokinetic data, including torso flexion/extension, torso rotation, and lift-task has been collected

on 70 normal subjects and 120 patients. Complementary clinical and psychometric assessment has been carried out on the patients. Subgroups of 20 normal subjects and 20 patients have repeated the complete isokinetic assessment on four occasions to examine test-retest reliability, inter-observer reliability, and learning effect. This data is being analyzed.

Future Plans—The final 18 months of this project will be devoted to the second objective of a controlled trial of isokinetic exercises versus non-isokinetic exercises for the treatment and rehabilitation of patients with low back pain. This is presently being planned.

[111] Programming Disorders in Fine Motor Skills: The Clinical Application of a New Assessment Procedure

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Sponsor: *Stichting Kinderpostzegels*

Purpose—The aim of the project is to implement a recently-developed procedure for the assessment of fine motor skills in a clinical rehabilitation setting. The procedure was developed at the Nijmegen Institute for Cognition Research and Information Technology (NICI) in close cooperation with the Department of Research and Development of the St. Maartenskliniek. The procedure enables clinicians to register fine motor behavior in an easy, objective, and patient-friendly way.

Methodology—Simple figures or trajectories are drawn by a patient on a digitizer using a pressure-sensitive pen connected to a computer. This set-up makes it possible to record movements (displacements of the pen) with a sample frequency of 100 Hz, and to analyze the movements in terms of the following kinematic variables: velocity, acceleration, pressure, fluency, movement time, and reaction time. The drawing as an end

result is not as important as the movements leading to it, which are the focus of the procedure; that is, changing the figure or the trajectory of specific aspects (number of repetitions, complexity, and/or direction of strokes).

Implications—Research revealed that the above-mentioned kinematic variables are sensitive to changes in the motor system caused by pharmacological agents, damage, fatigue, or therapeutic intervention. Aspects of the motor system are revealed that had remained hidden in normal clinical observations.

The method offers opportunities for analyzing the motor performance of children in a clinical context because the tasks are very simple and can be repeated many times (the normal behavioral repertoire of children). The method can be used in children over 4 years of age.

IV. Functional Electrical Stimulation

For additional information on topics related to this category see the following Progress Reports: [194], [285], [288], [352], [380], [381], [382], [384], [386], [390], [401], [518], [521], [534], [538], [540], [546], [547], [548], [567], [578], [610], [611], [616], [617].

A. General

[112] Comparison of Percutaneous Pudendal Nerve and Surface Electrical Stimulation for Bladder Inhibition

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Sponsor: VA Rehabilitation Research and Development Service (Project #B996-PA)

Purpose—We have been investigating functional electrical stimulation (FES) techniques to inhibit the bladder hyperreflexia that causes major morbidity and incontinence in the spinal cord injured (SCI) patient. Initial observations in our SCI cats have shown that FES techniques can inhibit the bladder. Therefore, we have begun testing SCI patients with various FES methods to attempt to alter their bladder hyperreflexia.

Methodology—Seven chronic upper motor neuron SCI males, in good health and stable urologically, underwent baseline cystometry (CMG) using 4-channel cystometry at 60cc/m fill rate. Then, inhibition of bladder activity was investigated using sacral surface stimulation, surface tibial nerve stimulation, rectal stimulation, surface penile base stimulation, and percutaneous pudendal nerve stimulation. Not all patients underwent all methods of stimulation. Stimulation was investigator-controlled using standard surface electrodes, rectal plug or percutaneous needles. Stimulation started at low voltage and frequency, adjusting voltage and frequency until the desired bladder inhibition or side effects resulted. Repeat CMG at various intervals recorded any changes.

Results—Successful bladder inhibition is indicated by an increase in bladder filling volume and a decrease in bladder pressure. In six of the seven patients we could cause some decrease in the bladder hyperreflexia using these methods. Sacral surface inhibition was least effective in diminishing bladder hyperreflexia. Penile stimulation, using surface electrodes at low frequency (< 5 PPS) and between 50-60 mA, may be most effective in inhibiting bladder hyperreflexia. Rectal, pudendal nerve, and peripheral nerve stimulation may be less effective inhibitors of bladder hyperreflexia.

Future Plans—Our goal is to find the most efficacious method of inhibiting bladder hyperreflexia. Surface stimulation at the penile base at low frequency appears to be the best FES method. We plan to design an appropriate electrode for chronic use of this FES method in an attempt to diminish the urological morbidity secondary to the hyperreflexic bladder.

Recent Publications Resulting from This Research

Treatment of Incontinence in a Spinal Animal Model: Comparison of Pudendal and Sacral Nerve Electrodes. Walter JS et al., in Proceedings of the American Paraplegia Society, Las Vegas, 1990.

[113] Improving Exercise Performance of Quadriplegics

Stephen F. Figoni, PhD; Satyendra C. Gupta, MD; Roger M. Glaser, PhD; Bertram N. Ezenwa, PhD; Agaram G. Suryaprasad, MD; Watson D. Parker, MD; Mary M. Rodgers, PhD; Steven P. Hooker, PhD; Pouran D. Faghri, MD, MS

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Sponsor: VA Rehabilitation Research and Development Service (Project #B587-RA)

Purpose—The purpose of this 3-year project is to finalize development and to evaluate an arm+leg exercise system for spinal cord injured (SCI) quadriplegics that maximizes active muscle mass and aerobic metabolism and allows adequate central and peripheral circulation. Arm-cranking is used to drive the leg-cycling motion, while a computer controls the functional neuromuscular stimulation (FNS) of appropriate leg muscle groups during the crank cycle to assist leg cycling. Phase I consists of modification of our current prototype voluntary-arm + FNS-leg ergometer to permit operation in either the upright sitting or supine posture. Phases II and III consist of evaluation of acute and chronic physiologic responses of quadriplegics during exercise testing and training with this device.

This project will produce a relatively low-cost system, techniques, and protocols for exercise testing and training of SCI quadriplegics. We will modify the present prototype of our upright arm+leg ergometer to overcome two physiologic obstacles facing exercising quadriplegics: posturally induced venous pooling and paralysis of a large muscle mass that potentially can be used for exercise. Technical modifications of the arm+leg ergometer will enhance venous return and activation of muscle mass. The data derived from this study should contribute toward optimizing methods for exercise testing and training of quadriplegics so that they can achieve substantially higher cardiopulmonary fitness levels.

Methodology—Each of the three phases of this project will take about one year. Phase I will entail the modification and reconfiguration of our present prototype arm+leg ergometer to accommodate supine posture. Modifications will involve: 1) placement of the arm-crank over the chest of supine subjects; 2) elevation of the leg crank to heart level to further enhance venous return; 3) supplementation of the FNS for quadriceps, hamstring, and gluteal muscle groups, with additional channels to stimulate calf muscles for enhancement of venous return;

and, 4) improvement of current computer programs to acquire/analyze data and to control multi-channel FNS exercise.

Phase II will involve assessment of acute physiologic responses during three modes of submaximal and maximal exercise performed in both upright sitting and supine postures. After recruitment of prospective subjects, informed consent procedures, medical screening, and habituation to FNS exercise, each quadriplegic subject will undergo graded submaximal and maximal exercise testing in both *sitting* and *supine* postures with (a) voluntary arm-cranking alone, (b) FNS leg cycling alone, and, (c) combined arm+leg ergometry.

Phase III will involve training of subjects for 15 weeks (3 days per week) using *upright* sitting arm+leg ergometry, then repeating the exercise stress tests.

Finally, subjects will train with *supine* arm+leg ergometry for 15 weeks (3 days per week) and repeat the exercise tests. Changes in physical fitness gained in the supine posture (over and above that gained in the upright sitting posture) will be determined.

All data collection procedures will be noninvasive (except for fingertip blood sampling) consisting of open-circuit spirometry, impedance cardiography and plethysmography, and auscultation. Dependent variables will include mechanical power outputs, systemic oxygen uptake and related respiratory variables; left ventricular stroke volume and cardiac output, myocardial contractile indices, and systolic time intervals; arm and leg segment arterial blood flows and fluid volumes; estimates of the proportions of cardiac output serving the arm and leg segments; arterialized capillary blood acid-base status and lactate concentrations; and arterial blood pressures. Data will be analyzed with parametric statistical techniques, that is, analysis of variance (ANOVA).

Progress—Design work on the ergometry system is in progress.

[114] Evaluation of FES Techniques for Exercise

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Sponsor: VA Rehabilitation Research and Development Service (Project #B433-RA)

Purpose—The purpose of this project is to objectively evaluate the effectiveness of functional electrical stimulation (FES) exercise techniques for improving health, physical fitness, and rehabilitation potential of patients with spinal cord injury (SCI). Specific objectives include: 1) assessment of acute physiologic responses and maximal performance during FES leg cycling (FES-LC) exercise, FES knee extension (FES-KE) exercise, voluntary arm-crank exercise (ACE), and combined FES-LC + ACE (HYBRID) exercise; and 2) determination of physiologic and psychologic adaptations resulting from training with the various FES/voluntary exercise modes.

Progress—Upon completion of 2.5 years of this 4-year project, 25 SCI subjects have completed at least one of the four 12-week training programs involving FES-induced exercise. Eight subjects have completed FES knee extension training, 20 have completed ERGYS training, 12 have completed serial FES-LC and ACE training, and 15 have completed hybrid training. An additional phase of interval training using FES-LC has been completed by eight subjects.

Preliminary Results—The acute physiological effects of FES-KE were examined during load resistances of 1 to 15 kg/leg in seven quadriplegics and seven paraplegics. Oxygen uptake, pulmonary ventilation, cardiac output, stroke volume, mean arterial pressure, and rate-pressure product increased slightly. Despite hypotension in quadriplegics, FES-KE appeared to be easily tolerated by all subjects. Training responses to FES-KE exercise were examined in seven SCI individuals. Following training, maximum load was significantly higher (5.7 versus 10.2 kg), thigh skinfold was significantly lower (20 versus 15 mm), and knee range of motion was significantly increased (125 versus 140 degrees). Since this form of FES training appears to strengthen paralyzed quadriceps muscle and improve knee range of motion, it may be appropriate in preparation for more strenuous FES activities.

Acute physiologic responses to FES-LC were examined in 30 SCI subjects (17 quadriplegics and 13 paraplegics) during a graded FES exercise test from rest to fatigue on an ERGYS 1 ergometer (Therapeutic Technologies, Inc.). For both groups, peak FES cycling significantly increased (from rest levels) mean oxygen uptake by 255%, and cardiac output by 69%. Mean peak power output for paraplegics (15 W) was significantly higher than for quadriplegics (9 W), eliciting higher peak levels of pulmonary ventilation and sympathetically mediated hemodynamic responses such as cardiac output, heart rate, and arterial blood pressures. Passive cycling without FES produced no statistically significant increases in physiologic responses above the resting level in either group.

Training responses to FES-LC were examined in 15 SCI individuals. Comparison of pre/post FES-LC training data showed significantly increased peak power output (43%), oxygen uptake (18%), and pulmonary ventilation (24%). Mean arterial blood pressure and total peripheral resistance during peak exercise tended to decrease after training, with no change in peak stroke volume. Most of the improved exercise performance following 12 weeks of training appears to be due primarily to peripheral adaptations that enhanced muscular strength and endurance. However, greater magnitudes of cardiopulmonary responses at the higher power outputs achieved post-ERGYS training could improve cardiopulmonary system training capability. This may be accomplished with more training time.

Simultaneous submaximal ACE and FES-LC exercises ("hybrid" exercise) results in additive metabolic and cardiopulmonary responses in most SCI subjects. Thus, hybrid exercise may provide for greater aerobic training capacities than ACE or FES-LC alone, especially in quadriplegics.

Future Plans/Implications—Psychological test results are being evaluated to identify correlates with subject attrition and fitness improvements. Physical indices are

being constructed to provide an overall representation of the physical progress made by each individual. These indices will be correlated with other physiologic and psychologic measures to determine relationships. Changes in paralyzed muscle strength and endurance are being documented using a computerized force-current measurement system.

Recent Publications Resulting from This Research

- Efficiency of FNS Leg Cycle Ergometry. Glaser RM et al., in Proceedings of the 11th Annual Conference of the IEEE/EMBS, 1961-1963, 1989.
- Force-Current Measurement System for Evaluating Muscle Performance During Functional Neuromuscular Stimulation. Ezenwa BN et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 179-180, 1989.
- Hemodynamic Responses of Paraplegics and Quadriplegics to Passive and Active Leg Cycle Ergometry. Figoni SF et al., ASIA Abstr Dig 80, 1989.
- Hemodynamic Responses of Quadriplegics to Arm, ES-Leg, and Combined Arm + ES-Leg Ergometry. Figoni SF et al., Med Sci Sports Exerc 21:2(Suppl.):S96, 1989.
- Peak Hemodynamic Responses of SCI Subjects During FNS Leg Cycle Ergometry. Figoni SF et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 97-98, 1989.
- Physiologic Responses to Simultaneous Voluntary Arm Crank and Electrically-Stimulated Leg Exercise in Quadriplegics. Hooker SP et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 99-100, 1989.
- Tibial Trabecular Bone Density vs Time Since Spinal Cord Injury. Rodgers MM et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 403-404, 1989.
- Acid-Base Balance After Electrically-Induced Leg Cycle and Voluntary Arm Crank Exercise in Paraplegics. Am Spinal Inj Assoc Abstr Dig 65, 1990.
- Acute Physiological Responses of SCI Subjects to FNS Knee Extension Exercise. Figoni SF et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 157-158, 1990.

- Automated Adaptive Equalization System for Asynchronous FNS-Induced Knee Extension Exercise for SCI Subjects. Ezenwa BN et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 159-160, 1990.
- Functional Neuromuscular Stimulation for Physical Fitness Training of the Disabled. Glaser RM, in Fitness for Aged, Disabled and Industrial Workers, 127-134, M. Kaneko (Ed.). Champaign, IL: Human Kinetics Publishers, 1990.
- Muscle Fatigue Characteristics with FNS-Induced Contractions. Kuntzman AJ et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 161-162, 1990.
- Physiologic Responses of Paraplegics and Quadriplegics to Passive and Active Leg Cycle Ergometry. Figoni SF et al., J Am Paraplegia Soc, 13(3):33-39, 1990.
- Training Responses of SCI Individuals to FNS-Induced Knee Extension Exercise. Rodgers MM et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 365-366, 1990.
- Characteristics of Functional Neuromuscular Stimulation-Induced Spasticity in Spinal Cord Injured Subjects. Rodgers MM et al., in Proceedings of the 8th Congress of the International Society of Electrophysiological Kinesiology (in press).
- Exercise Conditioning of the Spinal Cord Injured Via Functional Electrical Stimulation. Glaser RM, in Athletic Injuries to the Head, Neck and Face. 2nd ed., J.S. Torg (Ed.). Chicago: Yearbook Medical Publishers (in press).
- Fitness Following Spinal Cord Injury. Davis GM, Glaser RM, in Physiotherapy: Foundations for Practice Series, Neurology Volume, L. Ada, C. Canning (Eds.). London: Heinemann Medical Books (in press).
- Functional Neuromuscular Stimulation Threshold Elevation with Fatiguing Paralyzed Muscle. Kuntzman AJ et al., in Proceedings of the 8th Congress of the International Society of Electrophysiological Kinesiology (in press).
- Perspectives on Cardiovascular Fitness and Spinal Cord Injury. Figoni SF, J Am Paraplegic Soc (in press).
- Physiologic Responses to Prolonged Electrically-Stimulated Leg Cycle Exercise. Hooker SP et al., Arch Phys Med Rehabil (in press).
- Spinal Cord Injuries and Neuromuscular Stimulation. Glaser RM, in Current Therapy in Sports Medicine: 2, J.S. Torg (Ed.). Toronto: B.C. Decker, Inc. (in press).

[115] FNS Effects Upon Venous Pooling in Geriatric and Mobility-Impaired Patients

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Sponsor: VA Rehabilitation Research and Development Service (Project #B242-3RA)

Purpose—The overall purpose of this research program is to evaluate the acute effects of pulsatile functional neuromuscular stimulation (FNS)-induced contractions of leg muscles upon central and peripheral hemodynamic responses to determine if venous pooling/stasis can be

minimized and/or reversed in mobility-impaired and geriatric patients. Specific objectives are to evaluate the effectiveness of this FNS application for facilitating circulation during head-up tilt, upright sitting, standing, arm-crank exercise, and wheelchair propulsion.

Progress—Instrumentation that has been designed and constructed for implementing this research program include: 1) eight-channel neuromuscular stimulators, utilizing a less painful low-current electrical waveform to alternately contract thigh and calf musculature; 2) a motorized tilt table with adjustable arm-crank ergometer to allow arm-crank exercise during tilting; 3) an eight-segment impedance cardiographic/arteriographic data collection and analysis system to monitor central and peripheral circulation; and, 4) a system that measures bioelectrical resistance, reactance, and impedance in eight segments of the body simultaneously for assessment of segmental fluid shifts and fluid volumes. Both impedance systems are being used to assess physiologic responses during postural change, arm exercise, and effectiveness of FNS-activation of the skeletal muscle pump for minimizing venous pooling and enhancing venous return. Thirty-four elderly hemiplegic and other disabled geriatric subjects were initially screened by a physician and were given an orthostatic tolerance test. Twenty-eight of these subjects recently completed head-up tilt tests and are presently undergoing prolonged upright sitting tests incorporating periodic FNS-induced contractions of the leg muscles. Data from these tests are currently being analyzed. Subjects will next undergo the

prolonged standing test, followed by the arm exercise and wheelchair locomotion tests.

Future Plans/Implications—If this FNS application can reduce venous pooling in the legs and improve circulation to exercising arm muscles, it may be able to enhance arm exercise capacity, decrease the stressfulness of manual wheelchair locomotion, and improve the tolerance for upright postures for prolonged durations. Future medical and rehabilitative applications may also include prevention of deep venous thrombosis in immobilized or postsurgical patients and treatment of orthostatic hypotension, excessive pedal edema, and decubitus ulcers in susceptible individuals.

Recent Publications Resulting from This Research

- Arm Exercise Training for Wheelchair Users. Glaser RM, Med Sci Sports Exerc 21:S149-157, 1989.
- Cardiovascular Effects of ES-Induced Isometric Leg Exercise During Lower Body Negative Pressure. Davis GM et al., Med Sci Sports Exerc 21:S57, 1989.
- Cardiovascular Responses to FNS-Induced Isometric Leg Exercise During Lower Body Negative Pressure. Davis GM et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 95-96, 1989.

[116] Management of Central Ventilatory Insufficiency: Abdominal and Thoracic Stimulation

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—Current methods of phrenic nerve stimulation to relieve chronic ventilatory insufficiency have created problems with nerve damage and diaphragm inefficiency and fatigue. Diaphragm inefficiency may be related to the paradoxical inward chest movements during inspiration that occur when intercostal muscles are not activated. The goals of the present study are to develop improved functional electrical stimulation methods. Our approach will evaluate direct diaphragm stimulation to reduce problems of chronic nerve damage and to coordinate intercostal with diaphragm stimulation to improve efficiency and reduce fatigue problems.

Progress—In acute dogs following anesthesia, single intramuscular electrodes were implanted in each hemidiaphragm close to the entry of the phrenic nerves and bilateral electrode pairs were inserted deep into the chest wall to activate intercostal muscles. We found direct diaphragm stimulation alone capable of producing significantly large tracheal air flows. Intercostal stimulation alone produced thoracic excursions but reduced tracheal air flows. Combined diaphragm and intercostal stimulation produced tracheal air flows greater than diaphragm stimulation alone. These results indicate the feasibility of direct diaphragm stimulation and the

assistance provided by intercostal activation. We are now trying to optimize stimulating parameters and electrode placement to maximize the mechanical response.

Future Plans—We plan to determine if intercostal activity increases ventilatory efficiency and reduces

fatigue during long-term diaphragm stimulation. In addition, active expiration with “cough” may be possible with selective abdominal stimulation, thereby introducing a naturally induced clearing mechanism for the airways.

[117] A Study to Investigate the Effects of Functional Electrical Stimulation Exercise on Bone Mineral Density in Spinal Cord Injured Individuals with Disuse Osteoporosis

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This study is examining the effects of two different functional electrical stimulation (FES) exercise protocols on the bone mineral density of 1- to 15-year postinjury spinal cord injured individuals who have lost significant bone density due to disuse. The study is attempting to determine whether bone that has undergone major resorption can recover significantly. The key element being tested is the introduction of a resistive mechanical force to the exercise in addition to the forces generated by muscle activity. The results from this study will provide information that may help improvements in the design of existing FES exercise systems, thereby reducing the rate of loss of bone soon after injury, and consequently, the risk of fractures when walking is attempted.

Methodology—The two FES exercise systems being used in this study are the Regys 1 Clinic Rehabilitation System, and an ergometer system developed as part of this study that incorporates mechanical stimuli that emulate temporal loading patterns thought to optimally trigger bone remodeling. The latter system incorporates

current knowledge of appropriate stimuli for bone remodeling which will test the applicability of Wolff's Law for the recovery of bone lost due to disuse osteoporosis following spinal cord injury. This system provides exercise for the legs against a varying resistive force without compromising the aerobic benefits of the exercise activity.

Both male and female complete spinal cord injured individuals of between 1- to 15-years postinjury with significant bone loss are currently being recruited. The subjects are distributed between the two treatment groups and a control group who receive no specific exercise beyond their normal daily activities. The exercise treatment lasts 40 weeks for each subject.

Bone mineral density is measured at 10-week intervals in the neck of the femur, the shaft of the femur, and the lumbar spine, using dual photon absorptiometry (DPA). Total body calcium is also measured using DPA. In addition, the following laboratory investigations are performed: ionized calcium, parathyroid hormone, metabolites of vitamin D, bone Gla protein, calcitonin, and analysis of urine metabolites.

[118] Prevention of Secondary Complications in Spinal Cord Injury by Electrical Stimulation: Wheelchair-Attached Balance Frame

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Our objective is to establish a protocol for selecting and training appropriate patients to use a wheelchair-attached balance frame in conjunction with a two-channel stimulator to achieve transient periods of standing on a repeatable basis. We hypothesize that the wheelchair-attached balance frame will be accepted by patients as a device that does in fact enhance their activities of daily living and mobility.

Progress—Three individuals have now had field experience with the wheelchair-attached balance aid. Five individuals have had experience with the device in a controlled clinical setting. Standing time data indicate a frequency of use of greater than 10 times per week; however, patient comments have not been as positive as we had hoped. A total of four standing frames are now in the field evaluation.

Results—The major problem that appears to be preventing wider patient acceptance of the wheelchair-attached

balance aid is postural stability when attempting to release one hand to perform functional tasks. We have tried adding ankle-foot orthoses to enhance stability in two subjects, but trunk balance is a more difficult problem to solve. The transition from quiet standing in a controlled laboratory or clinical situation to field use will depend on correctly identifying the improvements that need to be made.

Future Plans—We plan to place additional balance frames in the field and to develop a satisfaction questionnaire for subjects to complete before and after their experience with the wheelchair.

Recent Publications Resulting from This Research

Functional Neuromuscular Stimulation for Standing After Spinal Cord Injury. Yarkony GM et al., *Arch Phys Med Rehabil* 71:201-206, 1990.

[119] Rehabilitation Engineering Center for Restoration of Neural Control

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Program Overview—The objectives of the Rehabilitation Engineering Center for Functional Electrical Stimulation at Case Western Reserve University (CWRU-REC) are to: 1) develop, test, implement, and evaluate clinical systems employing functional electrical stimulation (FES) technology which provide control of the extremities and stabilization of the trunk; 2) establish a model information exchange program providing information on FES for consumers, medical care providers, third-party payers and manufacturers; 3) deploy FES systems to other rehabilitation and research institutions; and, 4) transfer FES technology to private industry.

FES can be used in several ways to effect control of the nervous system. FES can control abnormal motor system function resulting from stroke, head injury, cerebral palsy, or scoliosis. It can also restore motor and sensory function loss due to paralysis resulting from spinal cord injury or stroke. In this program, we will address the problems presented by individuals with these injuries.

The program is organized to promote investigation in four priority areas: 1) development of a comprehensive FES information collection, referral, and dissemination program; 2) upper extremity FES and hybrid systems for

manipulation and grasp; 3) systems employing FES and orthotics to stabilize the trunk and correct trunk

deformities; and, 4) control of spasticity in stroke and head injury by FES.

[119a] I. Development of a Functional Electrical Stimulation (FES) Database and Dissemination Service

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Purpose—The FES Information Center was formed in December of 1988 to provide a wide range of information services to people interested in functional electrical stimulation (FES). The objectives of the FES Information Center are to: 1) develop and maintain a comprehensive information base on FES which will include journal articles, conference proceedings, progress reports, popular literature, videotapes, and other materials related to the use of electrical stimulation in rehabilitation; 2) disseminate the information in an accessible format to disabled consumers, medical care providers, service providers, third-party payers, researchers, and medical equipment manufacturers; and, 3) develop appropriate presentation formats for relating the current status of FES as described by the collated work of multiple investigators and facilities throughout the world.

Progress—Since our last report in 1989, the FES Information Center has experienced a surge of incoming requests for information, totaling 725 individual requests. About 95% of the inquiries were from United States residents representing 46 states. The remaining 5% of inquiries were from residents of about 15 different countries. Of the 725 inquiries, nearly 50% were made by individuals with disabilities or their family member/friend. About 30% of the inquiries were from persons providing services to individuals with disabilities, i.e., clinicians, rehabilitation counselors, or advocates. The remaining 20% represents inquiries from scientists, medical device manufacturers, third-party payers, journalists, and others. Due to the diverse nature of the inquiries and the lack of readily available information on the topic of interest, most inquiries were handled in a customized fashion whereby clients received some combination of reference materials, bibliographies, and referral information (see Future Plans).

We continue to collect information on FES for inclusion in our databases. Our FES Reference Database contains over 4,500 citations to FES-related reference materials. Our FES Research Directory database contains names, addresses, and descriptions of research projects for over 100 current FES researchers. Our FES Manufacturer's Directory database has been initiated with the identification (including names, addresses, and telephone numbers), of over 280 businesses producing FES equipment and supplies. We have established a referral arrangement with 45 FES service providers who have enrolled in our FES Clinical Services Directory database. We also maintain a FES Calendar of Events database and a FES Job Posted/Job Wanted database.

Other accomplishments during this period include publication of the *FES Update* newsletter (circulation 2,200), organization and videotaping of a 4-hour conference on FES for the lay public, representation at three national conferences and a survey of consumers of FES products and services.

Future Plans—Our future plans call for a comprehensive analysis of our information and referral experience thus far in an attempt to reduce the level of customization necessary to respond to incoming requests. The analysis will include more detailed client demographics and multidimensional profiles of client requests. We will use client evaluations to assist us in refining the type and level of service offerings we will make available in the future.

Recent Publications Resulting from This Research

Keeping Up on FES. Teeter JO, RESNA News 1(6), 1989.
FES and Stroke Rehabilitation. Teeter JO, Be Stroke Smart—
Newsletter of the National Stroke Association (in press).
FES . . . What's It All About? Teeter JO, Buckeye Banner:
Newsletter of the Buckeye Chapter, Paralyzed Veterans of
America (in press).

[119b] II. Development of Upper Extremity Control Employing Functional Electrical Stimulation

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Purpose—The objective of this project is to clinically evaluate the efficacy of FES hand systems which provide restoration of grasp and release for the high-level spinal cord injured individual. The first systems to be evaluated, designed for the C5 and C6 level quadriplegic, utilize chronically-indwelling, percutaneous, intramuscular electrodes and are configured to provide two functional hand grasps: palmar and lateral prehension/release. We have transferred this technology to four Centers in addition to our own, and carefully regulated and supervised trials are being performed to validate the findings of our own research. The four Satellite Centers are: (a) The University of Alberta (Edmonton, Alberta); (b) The University of Toronto, Hugh MacMillan Rehabilitation Centre, Lyndhurst Hospital (Toronto, Ontario); (c) Shriners Hospital for Crippled Children (Philadelphia, PA); and, (d) Rancho Rehabilitation Engineering Program (Los Angeles, CA).

During these studies, we will evaluate the level of functional hand control that can be restored to the high-level quadriplegic patient, and identify any limitations associated with the transfer of this type of clinical technology to other Centers. Controlled studies will be performed, using identical measurement methodology at each Center, to evaluate the efficacy of these system in providing enhanced independence in activities of daily living and quantitatively measured tasks. We will also document the reliability of the system and any sources of failure.

Progress—Major Achievements: The second in our series of Technology Transfer Workshops was successfully completed in March 1990, during which updates on protocols, procedures, hardware, and software were presented. Each Center reviewed their progress to date, and problems and experiences were discussed. To date, each Center has demonstrated the ability to successfully implement patients with the FES hand system (five in Philadelphia, two in Edmonton, two in Toronto, and one in Los Angeles). The results of the initial evaluations indicate that these patients are using their systems for

various activities (e.g., eating, drinking, writing, painting, shooting billiards). Functional evaluations and recruitment of additional subjects are ongoing.

We have succeeded in converting from a specific laboratory-based FES system to a standard, commonly accessible PC-based FES system that all collaborating Centers can utilize. These FES systems satisfy the technical specifications established for them and have exhibited few significant technical problems. Availability of the systems has been enhanced due to a successful technology transfer collaboration with industrial partners. Lastly, we have greatly increased our base of knowledge regarding the usefulness of our FES hand system to quadriplegic patients, thanks to the experiences and results reported by our colleagues at the collaborating Centers.

Barriers to Successful Technology Transfer: We have encountered several of the barriers that complicate successful technology transfer. In the clinical research setting, differing levels of available resources, facilities and personnel can affect the successful transfer and investigation of the device. Differences in the objectives and goals of the various groups evaluating the technology can create conflicts with the overall goals and objectives of the transfer project. In addition, the fundamental emphasis of each of those groups (e.g., basic research versus service delivery) impact the outcome of their investigations. Cultural differences amongst the evaluating Centers will influence how the particular device is deployed and evaluated at each, perhaps complicating evaluation of the data. Finally, the limited financial resources have required that the study be strictly focused and perhaps less encompassing than the collaborative investigators would have preferred.

Future Plans—During the coming year we will continue to recruit additional subjects into this study and to perform functional evaluations on all subjects who are enrolled. We will also continue to scrutinize the technology transfer process and to document any further limitations associated with it.

[119c] III. Electrical Stimulation in the Treatment of Scoliosis

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Purpose/Methodology—The objective of this study is to determine the efficacy of treating adolescent idiopathic scoliosis by electrical activation of the deep paraspinal muscles on the concave side of the curve. Prior investigations have demonstrated that at least one group of these muscles—the multifidi—are longer and less active on the concave side of the curve than on the convex side. In this study, we will measure the effect on spinal curvature of increasing the activity and decreasing the length of the multifidus muscles on the concave side of the curve. The multifidus muscles will be activated through percutaneous intramuscular stimulating electrodes attached to a multichannel, neuromuscular stimulator that was developed in our laboratory.

Fifteen adolescent subjects with idiopathic scoliosis will participate in this pilot study. Each will have three helically wound wire electrodes inserted percutaneously into the deep paraspinal muscles on the concave side of the curve. Electrical stimulation will be applied to the electrodes throughout the day in a pattern of 4 hours on, and 2 hours off. Curve correction will be monitored by inspection and by periodic radiographs. In the event of curve progression, the electrodes will be removed and the patient transferred to the Milwaukee brace program.

Each subject will participate in this study from the time of diagnosis until skeletal maturity (approximately 2 years), and will be followed for at least 1 year after stimulation has ended.

Progress—Progress on this project to date has been in three main areas: device design and construction, investigation of electrode placement, and fulfillment of regulatory requirements.

Device design and construction: One prototype stimulator and five patient stimulators have been constructed. The safety and durability testing required by the FDA is within 3 weeks of completion at the time of this writing. Following the completion of the testing, the devices will be ready for patient use. The stimulator weighs 300 grams and has the physical dimensions of $15 \times 10 \times 2.5$ cm. The device is powered by two C-lithium batteries; under operating conditions they are expected to last 6 to 8 weeks. Connectors and cables are being assembled at this time.

Investigation of electrode placement: Intraoperative studies continue to develop techniques for electrode placement. The innervation of the multifidus in the thoracic region appears to be isolated from the innervation to other paraspinal muscles; isolated contractions of the muscles have been easy to achieve in the cases studied to date.

Fulfillment of regulatory requirements: Full approval to initiate human investigations was received from the FDA in August 1990. We submitted an amendment to cover connector changes and began human studies in October 1990.

[119d] IV. Characterization and Reduction of Spasticity by Stimulation in the Hemiplegic Upper Extremity

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Purpose—The goal of this study is to improve upper extremity function in patients with hemiplegia by reducing spasticity and improving voluntary control by electrical stimulation. Efforts have concentrated on developing

methods of quantifying spasticity so that the effects of stimulation can be documented.

Quantification of spasticity by measurement of the increased resistance to joint rotation (stiffness) is

frequently complicated by changes in initial conditions. If this dependence can be quantified, and if it is repeatable, the spasticity and therapeutic methods may be measured more reliably.

Progress—By studying normal subjects, we have developed and tested quantitative methods of: 1) separating the passive, intrinsic, and reflex components of joint stiffness during single muscle contractions; 2) measuring the separate contributions of co-contracting antagonists to total joint stiffness; and, 3) measuring the reflex interactions between a pair of antagonist muscles during co-contraction. In a series of five subjects, the contributions of each of the three components to the total stiffness was significant, and could not be ignored. Since each component can be altered separately by stroke, it is

important to measure each of them separately. In a second study, we also observed that reflexes are exacerbated at moderate to high levels of co-contraction. The strength of reflexes measured during co-contraction was greater than the strength predicted on the basis of measurements made when each of the two muscles was contracting individually. The implication of this finding for measuring spasticity is that the loss of coordination is spasticity (resulting in co-contraction), which makes it important to take into account the contraction state of each muscle.

Recent Publications Resulting from This Research

Stiffness Regulation by Reflex Action in the Normal Human Hand.
Carter RR, Crago PE, Keith MW, *J Neurophysiol* 64:105-118, 1990.

[120] Bladder Evacuation by Direct Sacral Root Stimulation

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Electrostimulation to empty the neuropathic bladder has been the focus of our research for the past 12 years. In extensive animal studies, various sites of electrode implantation were evaluated—the spinal cord, pelvic nerves, detrusor muscle, and individual sacral roots. The most effective voiding was obtained by stimulation of the ventral component of selected sacral roots after their somatic contribution to the urinary sphincter had been sectioned.

During the past two years, six human volunteers underwent laminectomy and implantation of sacral root electrodes. Various combinations of dorsal rhizotomy versus separation, pudendal neurotomy versus selective somatic sectioning, were added to sacral root implantation. We also studied high- and low-frequency stimulation and pudendal nerve blockade by Xylocaine™ injection.

Preliminary Results—The preliminary results are most encouraging. This proposal is designed to investigate: 1) the possible harmful effect of dorsal rhizotomy on detrusor contraction; 2) the incomplete elimination of the

urethral sphincter by unilateral pudendal neurotomy, or unilateral selective sectioning of the somatic component alone; and, 3) the long-term effect of rhizotomy and somatic neurotomy on the sphincter muscles. Our animal experiments will carefully examine the effect of dorsal rhizotomy, pudendal and selective somatic neurotomy on bladder and sphincter function, as well as the metabolic and histologic changes in the sphincter muscles after these procedures. Ten patients (five men, five women) will undergo implantation over a 3-year period with a combination of different techniques aimed at achieving maximal bladder response and eliminating urethral resistance during stimulation while maintaining continence in the bladder filling phase.

Implications—We hope that, at the completion of this study, an effective, universally successful technique, devoid of harmful effects on the bladder and sphincter, will be available for general use to benefit the tens of thousands of patients with bladder and urethral dysfunction.

[121] Microstimulator for Functional Neuromuscular Control

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Purpose—This project seeks to develop and evaluate implantable, single-channel, untethered microstimulators for functional neuromuscular stimulation.

Methodology—The individual microstimulators will be small enough to be implanted by expulsion through a hypodermic needle. Up to 32 individually addressable stimulators will be powered and controlled by a single external coil. The microstimulator will consist of two electrodes sealed into opposite ends of a cylindrical glass capsule formed by drawing and melting a glass capillary tube. Within the capsule, a high- μ coil will receive power and command signals from an external transmitter coil by air-gap transformer coupling. These signals will be processed by a custom ASIC chip within the capsule. One electrode will be tantalum-pentoxide and

will also function as the main energy storage element of the implant.

Progress—During the past year, progress has been made in areas of microstimulator packaging and transmitter circuit design. Progress has also been made in obtaining a hermetic seal around the tantalum and iridium electrodes that exit at the ends of the transmitter. Good hermetic seals have been achieved around each wire. Further efforts will be directed at decreasing the length of glass-metal interface to minimize the package size. Using Class E driver circuitry, relatively efficient powering of the implants has been demonstrated. Methods to provide amplitude modulation of the carrier have been developed which will be used to transmit commands to the microstimulators. Preliminary plans for the ASIC chip are complete.

[122] Noninvasive Stimulation of the Human Central Nervous System

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—Recently, techniques have become available for the noninvasive stimulation of the human cortex and deep proximal peripheral nerves. Stimulation can be a high voltage, extremely brief electrical or magnetic pulse. One purpose of this study is to use these methods for noninvasive localization of different parts of the human cortex (including motor cortex, sensory cortex, and language cortex). Another purpose is to study cortical physiology in different disease states.

Results—The following are results of our study: 1) we established normative data for our own laboratory for measurement of central motor conduction velocities; 2) we found that electroencephalograms (EEGs) do not change after a session of cortical stimulation in normal volunteers and patients, which indicates the safety of the procedure; 3) we succeeded in mapping the hand, arm, leg, and mouth areas of the human motor cortex in

normal volunteers, correlating these motor maps with the sensory maps in patients with mirror movements, stroke, and with different types of amputations; 4) we found that patients with congenital mirror movements have a bilateral cortical representation of each hand in the motor cortex, and that they have physiologically active and fast conducting connections between the motor cortex and ipsilateral muscles in the upper extremity; 5) we studied hemispheric dominance for laryngeal muscles, finding that there seem to be bilateral projections from both hemispheres to motoneurons controlling muscles in both sides of the larynx, and that stimulation of the left hemisphere activates a larger percentage of the motoneuron pool bilaterally; 6) we mapped sensory cortex by utilizing the phenomenon of blockage of cutaneous stimulus; and, 7) we used magnetic stimulation to probe the processes in motor cortex during a reaction time task in patients with Parkinson's disease.

[123] Coatings for Protection of Integrated Circuits

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Purpose—Micromachined, thin-film recording and stimulating microelectrode probes, and miniature wires or cables connecting these electrodes with a source of control and power, must be protected for decades from the hostile ionic environment of extracellular fluids, if they are to be used reliably in humans. The long-term goal of this research is to develop biocompatible insulating materials which will permit these neural prosthetic implants to function reliably over the lifetime of an implant recipient.

Preliminary Results—A computer-based monitoring system has been developed that permits monitoring of leakage currents between an insulated wire and a saline soak bath. Leakage currents in the fA range can be

reliably measured, although the measurement may take as much as 2 days to allow transients to settle and to acquire adequate statistics. Eight commercially available polymers used for wirecoating are presently undergoing biased soak tests to evaluate leakage through the insulation. Of these, two materials (Teflon and a polyester) have shown leakage currents of below 1-2 pA/per cm² for over 1 year in soaking at potentials of plus and minus 5 V. This corresponds to a shunt resistance of about 100 million megohms per cm of 25 micron diameter connecting wire. Test chips that contain comb patterns have been insulated with a silicone polymer. These devices have maintained impedances of greater than 10 teraohms (10 trillion ohms) between conductors for over 6 months in a saline soak environment.

[124] Development and Evaluation of Safe Methods of Intracortical and Peripheral Nerve Stimulation

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Purpose—The evaluation of the effects of electrical stimulation on neural and surrounding tissues is the principal focus of this research project. The investigators are also evaluating the safety and effectiveness of silicon microcircuit stimulating probes and new biomaterials as they become available.

Results—Small elongated cysts containing red blood cells have been found in the cerebral cortex of animals near the sites of microstimulating electrode tips. It is felt that electrode insertion and/or movement can produce

damage to small blood vessels. The reason these micro-hemorrhages were not previously seen was because the tissue was not collected until several weeks after electrode insertion. This allowed macrophages time to clear out the erythrocytes, with subsequent collapse of the cysts.

Recent Publications Resulting from This Research

Histologic and Physiologic Evaluation of Electrically Stimulated Peripheral Nerve: Considerations for Selection of Parameters. Agnew WF et al., *Ann Biomed Eng* 17:39-60, 1989.

[125] Studies of the Electrochemistry of Stimulating Electrodes

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The objective of this research is to develop and evaluate electrochemically-safe stimulating electrodes for use in neural prostheses.

Results—New methods of applying activated iridium surfaces to stimulating electrodes have been developed. The corrosion properties of 316 LVM stainless steel have been studied as a function of the voltage across the

electrode-electrolyte interface. Some tentative "electrochemically-safe" operating limits have been established.

Recent Publications Resulting from This Research

Impedance of Hydrated Iridium Oxide Electrodes. Aurian-Blajeni A et al., *Electrochim Acta* 34:795-802, 1989.

Physicochemical Characterization of Sputtered Iridium Oxide. Aurian-Blajeni A et al., *J Mater Res* 4:440-446, 1989.

[126] Cultured Neuron Probe

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The objective of this research is to determine the feasibility of establishing direct and specific inputs to, and outputs from, the mammalian central nervous system (CNS). This would be accomplished by establishing connections between cultured neurons and target neuronal populations in the CNS, by developing and evaluating a brain probe containing the cultured

neurons, and electrodes for recording and stimulating them.

Progress—Rat neonatal hippocampal cells have been cultured on glial cells. Test wells simulating brain probes have been fabricated, and rat cervical ganglion cell neurites successfully grow out of the wells.

[127] Stimulating Electrodes Based on Thin-Film Technology

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The goal of this research is to develop multi-channel arrays of stimulating electrodes situated along the shank of a thin probe, capable of stimulating multiple small populations of cells in the central nervous system. Micromachining in silicon permits construction of arrays with electrode dimensions and spacings that will permit highly selective stimulation of small populations of

neurons. Active probes will be developed that integrate the electronics for 16 stimulators into the back of the probe.

Progress—Using activated iridium stimulating sites, charge delivery of greater than 3 mC/cm² has been achieved. Passive probes with electrode surface areas

ranging from 1,000 to $8,000\mu^2$ have been fabricated and characterized *in vitro*. Probes with five electrodes along the shank have been evaluated acutely *in vivo*. Design of the active electronics for a 16-channel probe has been completed.

Future Plans/Implications—Fabrication of the probe is expected in the coming year. This probe will permit

simultaneous control of the current levels at 16 electrode sites along the shank at an 8-bit level. The circuitry occupies about 6.4 mm^2 at the back of the probe.

Recent Publications Resulting from This Research

Batch-Fabricated Thin-Film Electrodes for Stimulation of the Central Auditory System. Anderson DJ et al., IEEE Trans Biomed Eng 36:693-704, 1989.

[128] Single-Channel Microstimulator for Functional Neuromuscular Stimulation

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose/Methodology—This project seeks to develop and evaluate implantable, single-channel, untethered microstimulators for functional neuromuscular stimulation. The individual microstimulators will be small enough to be implanted by expulsion through a hypodermic needle. Up to 32 individually-addressable stimulators will be powered and controlled by a single external coil. The implanted stimulator will consist of iridium electrodes fabricated at the ends of a micromachined silicon base. On this base, a power-and-control receiving coil, a charge storage capacitor, and a receiver-stimulator integrated circuit chip will be mounted. A glass capsule will cover these elements and will be hermetically bonded to the base.

Progress—During the past year, hermetic bonding of the Pyrex glass cover to the silicon oxide/nitride passivated silicon base has been demonstrated using anodic bonding. Hermetic encapsulation has also been demonstrated at thin-film conductive feedthroughs. Circuit blocks for portions of the stimulator have been designed and simulated in preparation to fabrication. A waffle structure is being investigated to increase the current carrying capacity of the electrodes. Using class E amplifier circuitry at 1 MHz, relatively efficient power transfer to the receiver coil has been demonstrated.

[129] Multichannel Multiplexed Intracortical Recording Arrays

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Purpose/Methodology—Penetrating microelectrodes with multiple recording sites for simultaneous, chronic recording of single unit activity from large numbers of neurons in the central nervous system (CNS) are desired by neural prosthesis researchers who need long-term connections with neurons for prosthetic control signals. This project aims to develop an implantable, multiple recording site probe suitable for chronic recording. Passive probes that contain five recording sites along the shank will be evaluated *in vivo*. Active probes containing up to 32 sites along the shank(s) will be fabricated and tested.

Progress—Over 20 different passive probes have been fabricated. Shank widths of 100 to 150μ for the standard probes and widths of 15 to 30μ for the nanoprobe have been fabricated. Shank lengths of up to 4.7 mm have been produced, as have probes with up to six shanks. Histopathological evaluation of nanoprobe implanted in guinea pigs for 5 weeks show minimal tissue reaction at distances greater than 10 to 15μ from the probe. Probes that incorporate a ribbon cable with the probe have recently been produced. These probes will be evaluated *in vivo* during the coming year. Probes that contain active

electronics at the back of the probe for three channels of amplification have been fabricated and used for chronic recording of single unit activity in the guinea pig. A 10-channel active probe that has amplification and multiplexing at the back of the probe has been fabricated and tested *in vitro*.

Recent Publications Resulting from This Research

Scaling Limitations of Silicon Multichannel Recording Probes. Najafi K, Ji J, Wise KS, IEEE Trans Biomed Eng 37:1-11, 1990.

Strength Characterization of Silicon Microprobes in Neurophysiological Tissue. Najafi K, Hetke JF, IEEE Trans Biomed Eng 37:474-481, 1990.

[130] Electrodes for Functional Neuromuscular Stimulation

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—Percutaneously-implanted intramuscular electrodes can provide smooth, rapid, and precise control of hand grasp in spinal cord injured individuals. The goal of this project is to improve percutaneous intramuscular electrodes and lead wires for use in functional neuromuscular stimulation to achieve reliable operation of a system utilizing up to 16 electrodes over a period of at least one year.

Results/Implications—Gold-coated stainless steel wire insulated with Teflon™ has been evaluated for strength,

ductility, electrical resistance, and resistance to corrosion under stimulation. Test electrodes in five cats have shown good survival rates. Histological examination of the tissue surrounding implanted electrodes has shown considerable variation along the length of the electrode, suggesting that localized contaminants on the electrode are responsible for reactivity. A pulse clamp method has been developed to measure electrode charge storage capacity.

[131] Dynamic Properties of Electrically Stimulated Muscles

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Sponsor: National Science Foundation

Purpose—In order to design a high-performance, implantable functional electrical stimulation (FES) system to restore function in paralyzed extremities, it is necessary to define the muscle models for optimal controller design.

Progress/Results—We determined the dynamic model of skeletal muscles subject to isometric and isotonic conditions and to various firing rates and recruitment control strategies. We also identified the model variations of nine

different muscles and the effect of tendon length on the model poles.

Recent Publications Resulting from This Research

Frequency Response Model of Skeletal Muscle: Effect of Perturbation Level and Control Strategies. Baratta RV, Zhou B, Solomonow M, Med Biol Eng Comput 27:337-345, 1989.

The Dynamic Response Model of Nine Different Skeletal Muscles. Baratta RV, Solomonow M, IEEE Trans Bio Med Eng 37:243-251, 1990.

[132] Control of Limb Joint by Co-Stimulation of Agonist-Antagonist Muscles

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Sponsor: *National Science Foundation*

Purpose—Voluntary motion of limb joint is accomplished by coactivation of its agonist and antagonist muscles. This should be duplicated when attempting to restore function to a paralyzed limb using electrical stimulation of muscles. This project investigates the patterns and function of voluntary coactivation for duplication in functional electrical stimulation (FES)-based systems.

Progress—To date, we found that the antagonist muscle is a most important organ in providing stable and regulated joint motion. First, it regulates against various external and internal disturbances, such as direction of

gravity, muscle moment arm, level of force required, etc. Secondly, it provides important stability to the joint, and especially to its ligaments, preventing damage and instability.

Recent study shows that the antagonist also regulates for joint velocity, allowing fast initial acceleration of the joint, as well as terminal braking to stop the motion.

Recent Publications Resulting from This Research

The Effect of Joint Velocity on the Contribution of the Antagonist Musculature to Knee Stiffness and Laxity. Hagood S et al., *Am J Sports Med* 18:182-187, 1990.

[133] EMG as a Force Feedback in Electrically Stimulated Muscle

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Sponsor: *National Science Foundation*

Purpose—Force feedback is necessary if regulation of stimulated muscle force output is anticipated. Since implantation of force sensors requires traumatization of the tendon, electromyography (EMG) is considered as a parameter representing force in a closed-loop paradigm.

Progress—To date, we determined the relations between EMG and stimulated muscle force after developing a sophisticated artifact suppression system. The relations were evaluated as a function of stimulation strategies (recruitment and firing rate), contraction rate, muscle

length, joint angle, and muscle moment arm. Additional work determined that the mean absolute value of the EMG is the most representative signal-processing mode for prediction of force.

Recent Publications Resulting from This Research

The EMG-Force Relations of Skeletal Muscle: Dependence on Contraction Rate and Motor Units Control Strategy. Solomonow M et al., *EMG Clin Neurophysiol* 30:141-152, 1990.
EMG Power Spectra Frequencies Associated with Motor Unit Recruitment Strategies. Solomonow M et al., *J Appl Physiol* 68:1177-1185, 1990.

[134] Computer-Controlled Orderly Stimulation of Motor Units in Various Strategies

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Sponsor: *National Science Foundation*

Purpose—The objective of this project was to develop and refine an electrical stimulation system that would allow orderly recruitment of motor units simultaneously

with firing rate changes in various control strategies similar to physiological modes known to occur under voluntary contraction. Such an approach will allow

smooth force generation, drastic reduction in fatigue, and possible damage to muscles.

Results—A computer-controlled stimulation system was designed, developed, and validated in a series of experiments which explored muscle dynamic properties which were not available to date. Further development reduced the number of nerve electrodes from two bipolar cuffs into a single tripolar cuff. It was found that similar results

could be obtained with intramuscular wire electrodes inserted in the motor point as well.

Recent Publications Resulting from This Research

Orderly Stimulation of Motor Units with Tripolar Nerve Cuff Electrodes. Baratta RV et al., IEEE Trans Bio Med Eng 36:836-843, 1989.

A Method for Studying Muscle Properties Under Orderly Stimulated Motor Units with Tripolar Nerve Cuff Electrodes. Baratta RV et al., J Biomed Eng 11:141-147, 1989.

[135] Modelling and Identification of Electrically Stimulated Muscle

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Sponsor: *Whitaker Foundation*

Purpose—In this project we are using animal preparations and human subject experiments to develop better models of electrically stimulated muscle. In particular, we are interested in how stimulated muscle force varies with stimulation activation, muscle length, muscle velocity, and muscle fatigue. A secondary goal is to develop rapid identification procedures for parameterizing the muscle models. Our goal is to use these models in designing controllers for FES systems which restore gait and grasp.

using nonlinear system identification methods. These methods were tested both in simulation and in animal experiments.

Future Plans—We will continue our animal experimentation with the objective of defining and identifying parameters for minimal muscles models which are still suitable for control. We will also validate our methods in human surface stimulation experiments.

Recent Publications Resulting from This Research

Methods For Estimating Isometric Recruitment Curves of Electrically Stimulated Muscle. Durfee W, MacLean K, IEEE Trans Biomed Eng BME-36(7):654-667, 1989.

Task-Based Control with an Electrically Stimulated Antagonist Muscle Pair. Durfee W, IEEE Trans Biomed Eng BME-36(3):309-321, 1989.

Modelling Electrically Stimulated Muscle. Robbins A, Masters thesis, Massachusetts Institute of Technology, 1990.

Modelling and Identification of Electrically Stimulated Muscle. Palmer K, Masters thesis, Massachusetts Institute of Technology, 1990.

[136] Muscle Stimulation Strategies for High-Contact Density Microstimulation Electrodes

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Sponsor: *Whitaker Foundation*

Purpose—There is a striking contrast between the normal, physiologic activation of muscle by the central nervous system (CNS) and activation of a muscle by functional electrical stimulation (FES). Artificially

induced contractions fatigue rapidly, are difficult to modulate for fine control, and demonstrate gross variation over short time-scales. One of the causes for this difference is the neural interface through which the

muscles are activated. The CNS has access to the motor neuron pool of hundreds or thousands of motor units per muscle which it modulates both by recruitment and by timing sequences to produce smooth, low-fatiguing contractions for finely controlled motion. In contrast, artificial stimulation is generally achieved with a single, gross electrode either wrapped around the peripheral nerve or applied over the surface of the muscle. Here, all muscle fibers are activated synchronously at high, fatiguing, stimulation frequencies to avoid muscle force ripple and with almost no control over individual motor units, resulting in an undesirable large to small motor unit recruitment order.

Recent advances in very large scale integration (VLSI) technology have led to the miniaturization of electronic components and opens the possibility of designing new neural stimulation interfaces which can contain hundreds or even thousands of electrode contacts, each of which could uniquely activate one or a few motor units. The goal of the research pro-

posed here is not to develop this electrode technology, but rather to determine how these future, high-contact density, nerve stimulation electrodes should be used to effectively recruit muscle activation in FES applications.

Progress—During the past year we have developed an acute animal model preparation where multiple axons of the rat sciatic nerve are stimulated and isometric force is measured in the triceps surae. Our relatively crude neural interface consists of arrays of standard wire microelectrodes. We plan to use three arrays of five electrodes each for a total of 15 stimulation channels.

Future Plans—When the preparation development is complete, we will commence experiments with the objectives of: 1) comparing stimulation algorithms; and, 2) developing advanced identification methods for determining the properties of the motor unit connected to each electrode channel.

B. Upper Limb Applications

[137] Functional Neuromuscular Systems (FNS) for Upper Extremity Control

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Sponsor: VA Rehabilitation Research and Development Service (Project #B011-4RA)

Purpose—The objective of this project is to implement a neuroprosthetic system which restores motor control in the paralyzed upper extremity of the high-level spinal cord injury (SCI) patient and to assess the efficacy of the system in improving the user's ability to independently perform activities of daily living (ADL) which are essential for independent functioning. The system provides controlled grasp/release by electrical stimulation of the paralyzed muscles of the forearm and hand. Clinical implementation is carried out first using a system employing percutaneous electrodes, and then progressing to an implantable receiver/stimulator system as consistent performance and usage of the hand system is demonstrated.

Progress/Methodology—*Part 1: Clinical Implementation and Evaluation.* There have been a total of 11 patients

recruited into the upper extremity study, six of whom continue to be studied under our clinical protocol. Four of the active patients have been monitored extensively using a patient survey technique. Clinical evaluation of system performance has focused on four primary methods of quantitative assessment of system usage: the Standardized Object Test (SOT), the Common Object Test (COT), the patient user survey, and the Subsystem Function Test (SFT).

In the SOT, repetitive object acquisition is performed over several sequential trials, allowing us to assess standardized functional performance. The SOT detects significant changes in consistency of patient performance over time, differences in performance across patients, and differences in performance with and without the hand system. In the COT, the patient's ability to perform

various integrated activities of daily living is evaluated, allowing us to assess more advanced functional performance. The COT is a descriptive test which includes measurements of the patient's level of independence and quality of performance in performing the activities. In addition, the patients indicate their preference in performing the activities with or without the neuroprosthetic system, how important the activities are to them, and how frequently they normally perform the activities. The patient user survey was introduced in 1990 to provide further documentation of which ADL tasks the patients perform during the day, which tasks they use their system for, and how often they use the system.

The SFT has been developed to allow quantitative evaluation and documentation of the system's input-output properties, the patient's control of their hand grasp, and the frequency response of the man-machine system. This test enables us to quantify user operation during laboratory evaluation and to identify elements of the system that are affecting performance. The input to the neuroprosthesis is a command signal generated by voluntary movement of the patient's shoulder and the outputs of the system are the position and force generated by the thumb (during lateral prehension) or the fingers (during palmar prehension). For the SFT, the system's output is defined as a single parameter, formulated by summing grasp opening (position) and normalized grasp force. The SFT utilizes visual pursuit tracking tasks, in which a target track and the system's output are displayed simultaneously on a color video display. The subject is asked to match the system's output to the target track as accurately as possible. These tests are presently underway.

Part 2: Neuroprosthetic System Development and Fabrication. Progress has been made in fabricating portable neuroprosthetic systems for outpatient usage, in development of the communications and the interface between laboratory computers and the portable systems, and in fabrication of implantable systems. Almost all aspects of development are completed with the transfer of tested prototype systems to industrial manufacturers' ongoing systems.

The manufacture of in-house devices for patient usage has been completed and all systems are presently in field test. Since the industrially-manufactured system is based on this in-house system, substantial effort has gone into tracking system performance. To date, no serious flaws in the system have been reported. The majority of system malfunctions have been traced to ongoing software revisions. The last development project with respect to the existing neuroprosthesis that is in progress is the refinement of the dual microprocessor software which governs its operation.

The implant stimulator system has continued to function successfully both *in vivo* and *in vitro*. Clinical evaluation of an 8-channel system implanted in a C6 complete SCI subject indicates that it continues to function to specification. The electrodes and implant stimulator have been implanted for 4 and 2 consecutive years respectively, with no significant changes in any of the system's input/output characteristics (e.g., recruitment properties, stimulation thresholds, and electrode impedance). No new subjects have been implemented with the implant stimulator system to date.

Preliminary Results—Part 3: Technology Transfer and Regulatory Affairs. Three primary objectives have been accomplished in the area of Technology Transfer and Regulatory Affairs. First, FDA approval was obtained in August 1989 to carry out a study of 10 subjects with the implanted system under an Investigational Device Exemption (IDE). This protocol allows us to use the devices manufactured in-house at Case Western Reserve University for the study. Second, transfer of the external patient portable system (NPS-IV) to a local manufacturer (Life Systems, Inc., Beachwood, OH) is complete and systems delivered. Third, the fabrication of 20 implantable receiver/stimulator devices (including all electrodes, leads, and in-line connectors) by a regional manufacturer (Biocontrol Technology, Inc., Indiana, PA) is complete and the units delivered. These devices are essentially identical to those manufactured in our own facility, with equivalent fabrication guidelines having been followed. These devices are earmarked for use in future implant applications in both upper and lower extremity projects.

[138] Optimizing Myoprosthetic Management with Microcomputers

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Purpose—The setup and assessment procedures employed for fitting myoelectric controls to child amputees were originally developed for adults, and are primarily implemented using subjective methods. This project evaluated old and newly developed management strategies, as well as establishing objective standards for the analysis of prosthetic operation.

We have focused on four steps that are normally performed during the fitting process. These are: 1) finding suitable muscle sites; 2) choosing a control system; 3) calibrating the control system; and, 4) training and assessing the amputee's ability to operate the system.

Methodology—During Year One, 30 amputees over the age of 6 years were tested to evaluate the reliability of a Myoelectric Control Assessment System, and to establish a database of prosthetic control measurements. Subjects in this group were asked to visit the Centre on three occasions (i.e., day 1, month 1, month 3). Two practice trials preceded testing on each visit.

Also during Year One, a Myoelectric Signal Assessment System (MSAS) was developed which encompasses the tools required by a clinician to objectively: 1) find the most appropriate muscle sites; 2) determine the amputee's suitability for a class of control systems; 3) determine the amputee's controlling myoelectric signal levels with the socket donned and weighted; 3) determine myoelectric signal variations produced during sustained muscle contractions and in various forearm positions; 4) determine antagonist muscle signal cross-talk and nonvoluntary co-contraction signals in order to minimize inadvertent activation of the prosthesis; 5) use the calculated calibration levels to calibrate the myoelectric control system; and, 6) check and verify calibration of the control system during follow-up visits and when either walk-in and mail-in service is required.

During Year Two, a second group of 19 amputees requiring refitting of their prostheses were tested to evaluate MSAS. We investigated how these procedures affected the operation of the myoelectric control system in compari-

son to that of the traditional procedures. This group of amputees was seen during normally scheduled fitting visits.

Results—Factor analysis of the data revealed five clear factors that most appropriately describe the performance of experienced myoelectric prosthesis users. These major measurement dimensions are: 1) Activity Factor: a measure of the total time to complete the task; 2) Under-shoot: a derived measure of the amputee's ability to control the open and close functions; 3) Accuracy (or Error): a derived measure of the amputee's ability to correctly select movements in the open or closed direction; 4) Overshoot: a derived measure of the amputee's ability to precisely control the system; and, 5) Strategy: a measure of the amount of time the amputee activated the control system relative to the amount of time required to complete the task.

We have also derived a simple method for calibrating the control system which minimizes poor operation for those amputees who experience co-contraction of antagonist muscles and who also find it difficult to discriminate muscle control. This simpler method may also prove useful for calibrating the control systems used by children.

Implications—The analysis of Year Two results clearly indicate that the microcomputer method resulted in performance levels which matched the traditional methods implemented by an experienced therapist using observations and amputee feedback. More importantly, the microcomputer method provided more complete information which documented the amputees' abilities, facilitated and complemented the clinicians' observations, and overcame the problems experienced with the traditional methods based on trial and error. In addition, case analyses indicated that for instances involving misleading feedback from the amputee, the microcomputer method was superior for calibrating the control system. This was particularly evident for subjects experiencing high levels of co-contraction of antagonist muscle groups, who then could not differentiate the switching levels of their control systems.

[139] Neural Net Control of FES-Aided Grasp Restoration in Quadriplegics

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Sponsor: *Massachusetts Institute of Technology, Newman Laboratory for Biomechanics and Human Rehabilitation*

Purpose—Neural nets show promise for controlling complex, nonlinear systems. By connecting large numbers of “neuron” elements in interconnected nets, through an iterative learning process, the controller can converge to a desired system behavior. In this project we are evaluating the use of neural net controllers in FES-aided quadriplegic grasp restoration devices. In the past, these systems have proved difficult to control, and require a lengthy period of trial and error calibration to determine appropriate stimulation sequences to restore useful grasp. By monitoring hand position and force output, a neural net controller should be able to iterate automatically to a set of acceptable stimulation sequences.

Progress—We are beginning a series of experiments using a simplified model of controlling stimulated thumb motion in a single degree-of-freedom. We have built an apparatus to measure thumb motion resulting from surface stimulation. We have also developed simulations of appropriate neural net controllers. An important objective of these experiments is to determine the length of time required to iterate to an acceptable control.

Future Plans—We will measure complete hand motion and force output due to stimulation using an Exos Dexterous Hand Master and instrumented objects. In a series of computer-controlled experiments, we will test the ability of neural nets to control FES grasp.

[140] Evaluation of Command Channels for Upper Limb Neural Prostheses

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Purpose—Upper limb neural prostheses use electrical stimulation to restore grasping function to quadriplegics. The user of such a system must have a signal channel to command the device to open and close the hand. The most common method for generating a command signal is to monitor motion of the contralateral shoulder. This project has the objective of: 1) exploring the limits on performance of upper limb neural prostheses imposed by the command channel; 2) evaluating novel command channels such as electromyogram (EMG); and, 3) developing assessment and prescription systems for optimizing command channel parameters for a particular user.

The basic approach is through an emulator of a functional electrical stimulation (FES) hand-grasp system. Subjects sit in front of a personal computer and the appropriate command channel being tested is monitored. For example, a sternum-mounted position sensor is used to detect shoulder position. An animation of a grasping task appears on the personal computer display. As the subject moves his real hand, the hand on the screen

moves, and as the subject manipulates his command channel, the animated hand opens and closes. The subject performs a simulated grasping task by manipulating and moving objects appearing on the screen. Performance is measured by the speed and dexterity with which the task is performed. The advantage of this emulator system is that parameters of the command channel can be changed while keeping the task constant, resulting in efficient cross comparisons.

Progress—We have conducted a series of tests of shoulder as a command channel in both able-bodied and quadriplegic subjects. The results demonstrate that optimal combination of shoulder-command channel parameters such as direction and range vary with individual subjects. This suggests the need for a prescription system which can evaluate each subject and determine the appropriate combination. We have also conducted a preliminary study of EMG as a command channel using able-bodied subjects. Results show that sufficient information transfer

is possible with EMG but at a reduced bandwidth. We are completing a redesign of our system hardware and software to ease the procedure for transferring our system into a low-cost prescription system and to enable 3-D tasks.

Future Plans—We will conduct a series of experiments in disabled human subjects to evaluate their ability to control tasks in 3-D. We will also generalize this research

approach to quantify the ability of disabled individuals to control multi-degree-of-freedom devices such as robotic aids, machine tools, and automobiles.

Recent Publications Resulting from This Research

Shoulder Movement as a Command Control Source for Upper Limb Neural Prostheses. Zahradnik J, Masters thesis, Massachusetts Institute of Technology, 1989.

[141] Prevention of Secondary Complications in Spinal Cord Injury by Electrical Stimulation: Wrist Extensor Strengthening

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The objective of this project is to develop an electrical stimulation protocol that will test the effectiveness of functional electrical stimulation (FES) and biofeedback in obtaining recovery of wrist extensors in the C4-C6 quadriplegic individual. Subjects for this research study are newly spinal cord injured quadriplegic individuals (less than 1 month postinjury) exhibiting manual muscle grade of greater than poor minus for biceps and/or anterior deltoid, and manual muscle grade of zero to fair for radial wrist extensors. Following intake evaluation and testing, all subjects will receive traditional splinting. The four groups consist of: 1) a control group; 2) a treatment group receiving only biofeedback; 3) a treatment group receiving only electrical stimulation; and, 4) a group receiving both biofeedback and electrical stimulation.

Methodology/Progress—Subjects with a total of 26 limbs being studied have successfully completed participation in this study. As of July 1990, data from 20 limbs have been analyzed with a two-way analysis of variance

(ANOVA). The dependent variables were: 1) amplitude of voluntarily produced EMG (i.e., change in microvolt read-outs); 2) manual muscle test; and, 3) evaluation of four graded self-feeding abilities—*a*) feeds self without use of wrist support (may use utensil); *b*) light finger foods (popcorn, chips); *c*) moderate finger foods (cookie, 1/2 sandwich); and, *d*) drink from 12 oz soda can.

The following scoring system was used: 0 = patient unable to perform; 1 = patient able to perform, not functional; 2 = patient able to perform functionally in clinic and other settings. These measurements were taken at the beginning and at the end of the 6-week test period.

Results—So far, the results of this statistical analysis do not show any significance for effectiveness among groups or interaction. It is unfortunate that two individuals in one group dropped out before final data could be collected. Thus, while the number of limbs was actually 28, the missing 2 data points caused 6 others to be omitted because of the need for equal sample sizes in each cell in this design. Data collection is still underway.

[142] Prosthetic Sensory Transducers

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Purpose—Prosthetic force and position transducers that can be attached to the fingers and hand are being developed for use by individuals with an insensate hand. This

research is directed toward making practical prosthetic sensors which are properly calibrated, miniaturized, and protected (encapsulated) for use in evaluating conscious

sensory feedback and closed-loop control of functional neuromuscular stimulation systems both in the laboratory and in tasks of daily living.

Progress—A multi-element force sensor that permits evaluation of the force at multiple points over the thumb

has been developed. A skin surface-mounted angle transducer that measures joint angle relatively independent of radius of curvature has been developed, and is being tested. Psychometric measurements to provide a mapping between force and position and electrical stimulation have been completed.

[143] Functional Neuromuscular Stimulation for Restoration of Hand Grasp

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The feasibility of neural prostheses based on functional neuromuscular stimulation (FNS) for the restoration of both palmar (pinch) grasp and lateral (key) grasp in spinal cord injured, quadriplegic individuals has been demonstrated over the past several years. The principal goal of this research project is to develop and evaluate ways to enhance the utility of FNS systems for hand grasp.

Specific tasks include: 1) evaluating closed-loop control systems, utilizing newly-developed artificial force and position transducers in quadriplegic human subjects; 2) determining the feasibility of integrating FNS wrist stabilization, FNS elbow control, and surgical procedures such as tendon transfer and arthrodesis into the FNS grasp system; 3) developing a biomechanical model of the hand for use in evaluating advanced FNS systems; and, 4) evaluating multiple degree-of-freedom closed-loop FNS control systems.

Progress—A computer-based system has been developed to allow advanced control algorithms and closed-loop control to be evaluated on individuals who are using a

percutaneous system for FNS. Data on muscle moment arm length as a function of joint angle are being collected for muscles of the hand. This information will eventually be used to develop a model of hand function that can be used to test new approaches to hand control. Implementation of an extended physiological perception (EPP) system for coupling information about hand force and hand position back to the contralateral shoulder has begun. Initial studies have been directed at characterizing shoulder muscles that can be electrically stimulated.

Recent Publications Resulting from This Research

Elbow Extension in the C5 Quadriplegic Using Functional Neuromuscular Stimulation. Miller LJ, Peckham PH, Keith MW, IEEE Trans Biomed Eng 36:771-780, 1989.

Implantable Functional Neuromuscular Stimulation in the Tetraplegic Hand. Keith MW et al., J Hand Surg [Am] 14A:524-530, 1989.

Synthesis of Hand Grasp Using Functional Neuromuscular Stimulation. Kilgore KL et al., IEEE Trans Biomed Eng 36:761-770, 1989.

Electrode Characterization for Functional Application to Upper Extremity FNS. Kilgore KL et al., IEEE Trans Biomed Eng 37:12-21, 1990.

[144] Effects of Nerve Electrical Stimulation on Upper Extremity Recovery Following Quadriplegia

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Purpose—Patients with cervical spinal cord injury commonly recover at least one segmental level of spinal cord function following their injury, and maximizing this

recovery of arm and hand function can greatly enhance independence. Standard therapy for this weakness includes range-of-motion exercises to maintain joint

mobility, strengthening exercises to reverse muscle atrophy, and functional training to restore functional use. Therapy may also include electrical stimulation to weak muscles. This nerve stimulation is clearly of benefit later in the recovery process in reversing muscle disuse atrophy. However, other recovery mechanisms are active during the early post-injury period, including resolution of upper motoneuron weakness, resolution of neurapraxia, and motor axon sprouting with reinnervation of denervated muscle fibers. The effects of nerve electrical stimulation on these early neural mechanisms are not well-known. This study examines the time-course of strength recovery in upper extremity muscle groups following cervical spinal cord injury, and the effects of nerve electrical stimulation on that recovery.

Methodology—One weak muscle group is selected for nerve electrical stimulation for 4 weeks, in addition to standard treatments. Another comparably weak muscle group in the opposite extremity receives only standard treatments. The rate and final level of strength recovery are compared for the electrically stimulated and the non-stimulated muscles.

Results/Future Plans—To date, 7 patients have completed the nerve electrical stimulation protocol. This data is being analyzed and additional subjects are being recruited. This study will document whether early nerve stimulation is beneficial in promoting recovery of strength. The long-term objective is to maximize functional recovery by directing appropriate therapies toward active recovery mechanisms.

C. Lower Limb Applications

[145] Computer Models for Designing FES Systems for Paraplegic Mobility

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Purpose—The long-term objective of this project is to develop computer tools to assist the rehabilitation team in designing functional electrical stimulation (FES)-control systems so that paraplegics can stand, walk, and perform other lower-extremity motor tasks.

Methodology—The dynamical equations of motion of the body segments for standing, walking, and other motor tasks important to the paraplegic will be generated and implemented on a computer. The musculoskeletal system will be modeled (including the paths of the lower-extremity musculotendon actuators) and the dynamics associated with these actuators will be computer-coded. A procedure will be developed to generate computer codes so that models can easily be constructed, thus making it possible to study a variety of lower-limb motor tasks. Computer codes will be generated to display, on a workstation, the computer simulations of FES-induced standing, walking, and the other motor tasks.

Progress—Using computer models and simulations, we have done the following: 1) studied the dynamical properties of FES-induced standing and walking; 2) found a feedback control for stimulating muscles that ensures stability of standing to large perturbations, and of walking to small perturbations; 3) studied standing, and the single- and double-support phases of walking; 4) determined the minimum number of muscles and strength needed to effect normal gait; 5) implemented, on a graphics workstation, an “animated” display of the lower-extremity musculoskeletal system to visualize the simulated standing and walking paraplegic; and, 6) studied how to establish an interactive computer environment for the development of models of neuro-musculoskeletal motor tasks.

Results—Our simulations suggest that FES-control automatic feedback controllers can be designed which would stimulate muscles in paraplegics to enable them to stand

for a long time without fatigue while they use their hands functionally to manipulate objects. Restoration of normal gait, however, will be much more difficult. We believe that a combination of FES and orthoses is necessary to restore functional ambulation to paraplegics in the near future.

Future Plans—We propose to provide clinical FES teams with interactive machine-independent software that will enable each team singly, or all teams in concert, to design FES controllers for pedaling, standing, and walking.

Recent Publications Resulting from This Research

An Interactive Graphics-Based Model of the Lower Extremity to Simulate Tendon Transfer Surgeries. Delp S et al., in *Advances in Bioengineering*, 1989 ASME Winter Annual Meeting in San Francisco, BED-15:167-168, B. Rubinsky (Ed.). New York: The American Society of Mechanical Engineers, 1989.

Muscle and Tendon: Properties, Models, Scaling, and Application to Biomechanics and Motor Control. Zajac FE, *CRC Crit Rev Biomed Eng* 17(4):359-411, 1989.

Paraplegic Standing Controlled by Functional Neuromuscular Stimulation: Part I—Computer Model and Control System Design. Khang G, Zajac FE, *IEEE Trans Biomed Eng* BME-36:873-884, 1989.

Paraplegic Standing Controlled by Functional Neuromuscular Stimulation: Part II—Computer Simulation Studies. Khang G, Zajac FE, *IEEE Trans Biomed Eng* BME-36:885-894, 1989.

Restoring Natural Gait to Paraplegics through Functional Neuromuscular Stimulation: A Feasibility Study. Yamaguchi GT, Zajac FE, in *Issues in the Modeling and Control of Biomechanical Systems*, 1989 ASME Winter Annual Meeting in San Francisco, DSC-17:49-57, J.L. Stein, J.A. Ashton-Miller, M.G. Pandy (Eds.). New York: The American Society of Mechanical Engineers, 1989.

Modeling FES Actuation and Control of Multisegmental Limb Movements. Yamaguchi GT, Zajac FE, in *Proceedings of the American Control Conference*, San Diego, 1990.

A Musculoskeletal Model of the Human Lower Extremity: The Effect of Muscle, Tendon, and Moment Arm on the Moment-Angle Relationship of Musculotendon Actuators at the Hip, Knee and Ankle. Hoy MG, Zajac FE, Gordon ME, *J Biomech* 23:157-169, 1990.

[146] Improvements in the Gait and Strength of Post-Surgical Patients Due to Electrical Stimulation

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Sponsor: Boston University, Biomedical Research Faculty Seed Grant, Graduate School; Foundation for Physical Therapy; Dudley Allen Sargent Research Fund; NeuroMuscular Research Center

Purpose—The purpose of this study was to ascertain the effects of electrically-elicited co-contraction of the thigh muscles on isokinetic thigh muscle strength and gait in patients after anterior cruciate ligament surgery. Ten patients who had undergone ligament reconstruction were randomly assigned to one of two treatment groups: neuromuscular electrical stimulation (NMES), and volitional co-contraction (VC).

Methodology/Results—After 4 weeks of rehabilitation of the quadriceps femoris and hamstring muscles, a post-test design was employed to assess the differing effects of the two rehabilitation regimens on muscle strength and gait parameters. Muscle performance analysis consisted of isokinetic measurements of peak torque and average torque at different degrees of knee flexion. The average torques and the peak torques were found to be significantly greater in the NMES group than in the VC group.

There were no significant differences between the two groups in any measures of the hamstring muscle performance.

Gait analysis was performed with the use of the WATSMART optoelectronic motion analysis system and the TRACK rigid body analysis software. There was a significant difference in stance time between the involved limbs as a function of treatment. The cadence and walking velocity of the NMES group were greater than that of the VC group. The stance phase knee flexion and extension data for the involved knee were qualitatively different from that of the uninvolved knee in all subjects. Quadriceps femoris muscle performance measures and knee flexion excursion during stance were highly correlated. The decrease in quadriceps femoris muscle performance found in patients after anterior cruciate ligament reconstruction was significantly attenuated by the addition of NMES to the treatment regimen.

[147] Fatigue of Paralyzed Muscles Activated by Functional Electrical Stimulation in Paraplegics

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Sponsor: *Israel Ministry of Defense; Segal Foundation; Technion VPR Fund; Montreal Biomedical Research Fund;
Archie Micay Biomedical Research Fund*

Purpose—The objectives of this project are to study noninvasively the process of fatigue of paralyzed muscles of paraplegic patients, externally activated by functional electrical stimulation (FES).

Progress/Methodology—Dynamometers were designed and constructed for on-line monitoring of the decaying muscle force output under both isometric and isotonic conditions. The myoelectric activity was measured by means of surface electromyogram (EMG) of the fatiguing muscle. The metabolic state of the activated muscle was obtained by using noninvasive P-31 magnetic resonance spectroscopy (MRS) of the stimulated muscle, on a Gyrex 2T magnetic resonance imaging (MRI) instrument. Each of the myoelectric and metabolic measurements was coupled with the measurement of the muscle force output. In this way, correlations between force and EMG, as well as force and metabolic state, were obtained.

Results—Under sustained stimulation conditions, the force in the quadriceps muscle was found to decline to 50% of its initial value after the first minute, to 30% after the second minute, and to 25% after the third. From the EMG parameters measured, the peak-to-peak amplitude of the compound muscle action potential (CMAP) was selected to represent the myoelectric activity of the muscle, and was found to decrease in the course of fatigue. Our results on EMG-force correlation reveal a nonlinear correlation (power curve-fit), between these two parameters in the first 60% portion of the

fatiguing process.

P-31 MRI measurements included the high energy compounds (adenosine triphosphate [ATP] and phosphocreatine [Pcr]). The inorganic phosphate (Pi) level at rest was too low to be detected on this machine. However, FES induced a pronounced variation in these components: as Pcr levels declined, the Pi peak increased with fatigue. The intracellular pH could be calculated from the chemical shift between the Pcr and Pi peaks; this parameter was found to decrease during fatigue and to increase back towards its rest value in the recovery process. One additional peak was found to build up during fatigue, that of phosphor-mono-ester (PME), reaching values even higher than those of Pi. Correlation of this force with each of the metabolic factors was found to be strongly nonlinear.

The recovery of the muscle following fatigue could be established by using the very same parameters. Among all the metabolic parameters analyzed, PME had the slowest rate of disappearance, with the longest half recovery time. This parameter, which accounts for the long-term fatigue of the system, could thus be considered as an indicator of full recovery of the muscle.

Recent Publications Resulting from This Research

Recruitment, Force and Fatigue Characteristics of Quadriceps Muscles of Paraplegics Isometrically Activated by Surface FES. Levy M, Mizrahi J, Susak Z, *J Biomed Eng* 12(2):150-156, 1990.
The Time-Dependent Output of Paraplegic's Quadriceps Muscles Activated by FES. Levy M et al., in *Advances in External Control of Extremities X*, 555-569, D.B. Popovic (Ed.), Nauka, Yugoslavia, 1990.

[148] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: Neural Network Controllers for FNS Locomotion

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B193-4RS)*

Purpose—Recent advances in artificial neural network technology indicate that this is a promising technique for use in functional neuromuscular stimulation (FNS)

control systems. Neurobiological studies have demonstrated some of the intrinsic neuron properties and interneuronal connections used by biological systems

to generate cyclic motions. Models of these neural networks have been used to simulate the locomotion of insects as well as other cyclic motor acts. Such pattern-generating networks may be particularly useful in lower extremity FNS systems. With the eventual incorporation of feedback and learning, such networks may provide significant improvements to current lower extremity FNS systems. The purpose of this work is to explore the potential of pattern-generating neural networks for producing stimulation patterns to be used for lower extremity FNS locomotion. Preliminary studies reported here were directed at designing pattern-generating neural networks which exhibit specific characteristics that may be important characteristics for the FNS control system.

Progress/Methodology—Our preliminary studies have focused on the development of three pattern-generating networks: one which allows for straightforward modulation of cycle period, a second which generates a six-phase oscillation to correspond to six phases of gait, and the third network incorporates reflexes and modulates their effects with phase of oscillation.

The first network consists of two neurons in mutual inhibition. The intrinsic properties of the neurons and their influence on each other result in a oscillatory

pattern of activation; the period of this oscillation can be varied by changing one parameter of each of the neurons. Such a network may be useful as the core of a locomotion controller so that step-cycle frequency could be varied. The second network consists of six neurons, each oscillating at the same frequency, but phase-shifted with respect to each other. The timing of the activation of the neurons is such that each of the neurons would correspond to one of six phases of gait (left-weight acceptance, push-off and swing; and right-weight acceptance, push-off and swing). The third network incorporates modulated reflexes into the oscillatory pattern of activity. A stimulus given to the network results in a change in the nominal cyclic pattern, but the nature and magnitude of the change depend upon the phase during which the stimulus was given. This modulation of reflexes might be useful, for example, to elicit stronger flexion if the leg is flexing when the stimulus arrives, or stronger extension if the leg is weightbearing when the stimulus arrives.

Future Plans—Future work will focus on applying these neural network pattern generators to models of FNS-activated neuromuscular systems. Issues to be considered will be multi-joint coordination, incorporation of feedback for event detection and servo-type control, and adaptation to make adjustments for changing system parameters.

[149] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: FNS Walking in Paraplegics

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Purpose—The long-term goals of this study are: 1) to develop practical neuromuscular stimulation systems (FNS) to restore ambulatory movement in paralyzed people; and, 2) to use functional neuromuscular stimulation (FNS) as a motor retraining tool in paretic individuals. Our objective is to develop current percutaneous FNS systems into implantable, reliable, cosmetic, self-adjusting devices which will provide paralyzed people with ambulatory mobility in the home and workplace.

Progress/Methodology—After several earlier electrode designs were found to be short-lived, we developed a compound helix electrode connected to a percutaneous

lead for chronic muscular stimulation. This electrode is implanted without a surgical incision by probing the target muscle with a 26-gauge needle and then inserting the electrode to the motor point through a 15-gauge cannula. Postimplantation electrodes are monitored and removed if there is: 1) a persistent infection or rejection reaction; 2) an increase in impedance indicating breakage of the electrode or lead; or, 3) an adverse change in muscle response to electrical stimulation (e.g., decrease in muscle force, pain during stimulation, stimulation of unwanted muscles).

The compound helix design has been used for 2 years. Forty-five electrodes have been implanted in the ankle flexor/extensors (soleus, gastrocnemius, tibialis

anterior muscles) with 80% surviving; 215 in the hip flexors/adductors/abductors (quadriceps, sartorius, tensor fasciae latae, gracilis, adductor longus, posterior adductor, gluteus maximus, gluteus minimus, and gluteus medius muscles) with 68% surviving; 82 in the hamstring muscles with 55% surviving; and 37 near spinal roots to stimulate the quadratus lumborum, erector spinae, and iliopsoas muscles with 37% surviving.

This study currently involves six paraplegic subjects. All of them can stand using their FES systems. Three of them can walk, one consistently over 300 meters at a speed of 0.5 m/sec with a walker for support. He can climb stairs with two rails independently. On stairs with one rail, he needs a crutch or a person for support. He can do side-stepping and has used his FNS system outside the lab with assistance to overcome structural barriers.

We have made preparations to implement a one-hand support standing system using an 8-channel implantable stimulator. This involved modifying our external controllers to power and control the Case Western Reserve University (CWRU) 8-channel implantable stimulator/receiver, and refining the surgical protocol and testing hardware through animal implantation.

We are collecting normal data with the Motion Analysis (MA) system for comparison with paralyzed subject data. We developed software to synchronize MA data with stimulation patterns, to provide a tool for improving the programming of ambulatory functions in subjects.

During our study of muscle fatigue due to electrical stimulation, we observed increased muscle fatigue with reduction in rest time between stimulation bursts, with increase in stimulation frequency, and with increased resistance to motion.

We found control of knee flexion at the heel strike

and during push-off to be critical to progression in walking; temporal coordination of muscle activity in certain phases of the gait cycle to be critical to less than 20 ms; and, that a delay determined by trial and error produced smoother walking than triggering of the next step by foot pressure sensors.

We measured the intra-compartmental pressure in the anterior tibial compartment in five paraplegic subjects during continuous and cyclic stimulation. The compartment pressure was within normal ranges both before and after FNS exercise.

Results—Over a 10-year period, we have evaluated three generations of a portable percutaneous FNS system in 24 subjects, including 15 paraplegics with complete neurological injuries and 5 hemiplegics/hemiparetics. The FNS system provided standing capability for all of the paraplegic subjects and nine of them were able to walk. In addition, three relatively new subjects are expected to be able to walk in the near future. All hemiplegic/hemiparetic subjects demonstrated improved mobility with FNS.

Recent Publications Resulting from This Research

Metabolic Responses to Arm Ergometry and Functional Neuromuscular Stimulation. Edwards BG, Marsolais EB, J Rehabil Res Dev 27(2):107-114, 1989.

A Double Helix Electrode for Functional Electrical Stimulation. Scheiner A, Marsolais EB, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 373-374, 1990.

Fatigue of Electrically Stimulated Muscle in Paraplegic Subjects. Kobetic R, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 371-372, 1990.

A Portable 32-Channel Data Collector. Ferguson KR, Borges GA, Kobetic R, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 391-392, 1990.

[150] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: Implant Devices for Lower Extremity FNS Systems

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Sponsor: VA Rehabilitation Research and Development Service (Project #B193-4RS)

Purpose—The purpose of this research was to develop intramuscular electrodes to be used with an implantable stimulator.

Progress/Methodology—We developed an electrode for skeletal muscle stimulation designed to be implanted without a surgical incision. The electrode is manufac-

tured by forming stainless steel, Teflon-insulated wire into a double helix configuration. This geometry provides stress relief to the electrode during muscle contractions. The electrode tip is augmented with stainless steel barbs to increase anchoring strength. For implantation, we mount the electrode on a 26-gauge needle and insert it through a 13-gauge needle to the motor point. We then

pass the lead (7-stranded 316L wire wound around a prolene core and placed inside a Silastic sheath) subcutaneously (with a 16-gauge passing tube) to a connection site where it is attached to an implantable-stimulator lead. We fit the proximal end of the electrode with a "pin and spring" type connector to make the electrode/stimulator connection.

A second intramuscular design was developed at Case Western Reserve University (CWRU) with collaboration from this project. The major difference between this electrode and the one described above is that the stimulating end has a polypropylene anchor for stability and deinsulated wire wrapped around the Silastic tubing for the conducting surface. Two studies were conducted to evaluate this design *in vivo*. In the first, we conducted preliminary animal evaluation involving the implantation of four surgically-implanted intramuscular electrodes and four epimysial electrodes connected to an implantable neuromuscular stimulator. The intramuscular electrodes all operated properly throughout the 14-week study, producing functional responses indistinguishable from the epimysial electrodes. In the second study (still active) we implanted eight electrodes (connected to implantable stimulators) in two dogs (four for 1 year and four for 2 years). No problems (electrode breakage, infection, etc.) have been observed.

We have developed a modified arthroscope technique to increase the accuracy of electrode insertion for functional neuromuscular stimulation (FNS). The current FNS technique for determining the optimum site for percutaneous electrode implantation is to stimulate the target nerve or muscle with a 26-gauge probe using anatomic guidelines. This method lacks accuracy because there is no direct visualization of where the probe or elec-

trode sits unless an open incision is made. Using a clear polyvinyl fluoride sheath over an arthroscope inserted through a 1 mm stab incision, a technique similar to that described by Okutsu, we have demonstrated the feasibility of visualization of the sciatic nerve and its branches in the feline model. The nerves can be identified by their distinctive vascular markings and followed with minimal disruption of the soft tissues. In this way, individual branches can be identified and targeted for instrumentation, allowing selective stimulation of specific muscle groups. We further demonstrated the practicality of percutaneously implanting an electrode beside a target nerve under direct visual control with the scope.

Implications—The polyvinyl fluoride sheath over the arthroscope allows effective soft tissue scoping by gently opening a path through the connective tissues and providing an unimpeded field of view. This alone offers diagnostic advantages for the study of nerves. For our needs, it offers a minimally invasive means of electrode insertion under direct visual control. Soft tissue scoping in the feline model is a practical procedure that has applications for diagnostic studies on nerves and will allow accurate FNS electrode placement.

Recent Publications Resulting from This Research

The Design and Evaluation of a Surgically-Implanted Intramuscular Electrode for Use with an Implantable Stimulator. Memberg WD, Masters thesis, Case Western Reserve University, 1989.

Using a Modified Arthroscope to Augment the Accuracy of Electrode Insertion for Functional Neuromuscular Stimulation. Doyle J, Scheiner A, in Proceedings of the 18th World Congress Societe Internationale de Chirurgie Orthopedique et de Traumatologie, Montreal, 1990.

[151] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: FNS Systems for Gait Assist and Motor Retraining in Stroke and Head Injury Subjects

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Sponsor: VA Rehabilitation Research and Development Service (Project #BI93-4RS)

Purpose—The long-term goal of this study is to determine the efficacy of using functional neuromuscular stimulation (FNS) in the rehabilitation of hemiparetic and hemiplegic patients. The hypothesis to be studied is: FNS used for gait and motor retraining in paretic stroke patients will improve motor control, the speed and

cosmesis of gait, and the safety of walking, stair-climbing, and other functional maneuvers.

Results—Systems using intramuscular electrodes with percutaneous leads have been developed and tested in paretic patients who demonstrated significantly improved

function. In additional preparatory work, this laboratory has reported therapeutic use of implanted electrodes controlled through computerized stimulation patterns of gait for stroke subjects. We found improved gait and endurance for a mildly impaired subject; and for a severely involved (12-months poststroke) nonambulator, the percutaneous FNS system resulted in the ability to ambulate 80 feet numerous times, using a hemi-walker.

Restoration of function for hemiplegics. Case study video data showed that with FNS, functional status improvement was achieved for 100% (4/4) of the hemiplegic subjects treated. Functional improvement was from wheelchair mobility to ambulatory status of various levels.

Restoration of function for head injury diagnosis. Case study videotape showed, for a head-injured subject, a progressive 9-month improvement in motor function, ambulatory status, and functional activities of daily living (ADL). Hip flexor strength improved from gravity-eliminated joint movement to effective hip flexion against gravity during gait swing phase. Motor function improvements included achievement of right and left swing phases without FNS. Ambulatory status improved from wheelchair mobility to ambulation with Lofstrand crutches and stand-by assist. Functional ADL capabilities included stair ascension without FNS and descension with FNS. A home assessment was made and goals have been formulated for home use of the FNS system. Because of the possible confounding variable of spontaneous recovery, one or two case studies cannot conclusively determine the efficacy of FNS for treating head injury motor deficits. However, improvements in motor deficits occurred in this case, in close temporal relationship to specific FNS treatment, suggesting a cause and effect relationship.

FNS and movement retraining for hemiparetics. Case study videotape and kinematic data indicated gait pattern improvement following a combination of treatment with

FNS-driven movement, movement retraining, and FNS-controlled movement retraining. Improvements were documented for swing-phase ankle dorsiflexion, hip and knee flexion, and pelvic control, during slow cadence (56 steps/min) gait with conscious attention on the part of the subject. Further study will determine if the new pattern can be learned for faster walking speeds and for use at the subconscious level.

Future Plans/Implications—Ongoing and future studies have the following goals: 1) specify and test a movement difficulty scale and treatment progression protocol; 2) design and test FNS drive and assisted exercises for retraining isolated joint movement; 3) identify decision-making criteria for creation of exercises which improve motor control; 4) adapt the FNS system with improved user/system interfaces for those with visual and upper extremity disability; and, 5) test the practicality of a totally-implanted FNS system for future use in a clinical setting. Outcome measures used to identify benefits will be gait analysis, muscle function evaluation, testing of functional maneuvers, and evaluation of the ease of use of the FNS system by patients and therapists. This research will yield new information regarding the benefits of specific FNS-driven and assisted exercise, and decision-making criteria for designing rehabilitation FNS exercise for individual cases for clinical use.

Recent Publications Resulting from This Research

FNS Application for Restoring Function in Stroke Patients.

Marsolais EB, in Proceedings of the 11th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Seattle, 829-830, 1989.

Percutaneous FNS Implementation to Improve Ambulation in Stroke Subjects. Kobetic R, Marsolais EB, in Proceedings of the 12th Annual RESNA Conference, New Orleans, LA, 103-104, 1989.

Stroke Gait Correction with Multi-Channel FNS. Marsolais EB et al., in Proceedings of the 36th Annual Meeting of the Orthopaedic Research Society, New Orleans, LA, 553, 1990.

[152] Nonlinear Controllers for FES-Aided Gait

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Sponsor: National Center for Research Resources, National Institutes of Health

Purpose—One of the difficulties in controlling FES-aided paraplegic gait is that muscles are nonlinear, time-varying actuators. We are evaluating the effectiveness of advanced nonlinear controllers to control these systems.

Progress—In a series of simulation studies and a preliminary series of human experimentation, we have implemented adaptive and nonadaptive forms of sliding controllers, a control structure which is well-suited to

systems which cannot be modeled precisely. Although the simulations demonstrated that sliding controllers showed great promise, the initial human experimentation, which had the objective of position control of the unloaded shank, proved to be disappointing. The controllers are being redesigned to include a more detailed muscle model.

[153] Closed-Loop Control of Functional Neuromuscular Stimulation Using Implantable Force Sensors

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation; Medical Research Council of Canada; Muscular Dystrophy Association of Canada; Rick Hansen Man-in-Motion Legacy Fund; Network of Centres of Excellence of Canada*

Purpose—The purpose of this project is to evaluate in an animal model a new approach for closed-loop control of electrical stimulation of paralyzed muscles, in which signals from implanted *nerve cuff recording electrodes* provide feedback that is used in the control of FNS.

Progress—In anesthetized cats, hindlimb muscles were activated through permanently implanted intramuscular electrodes using FNS, with the objective of having the foot press against and hold an object that would otherwise fall. Stimulation to produce the necessary force on the footpad was controlled either in open-loop form or using feedback from a force sensor. Signals recorded from cuff recording electrodes implanted on a sensory nerve that supplies the footpad were analyzed to extract information on the force applied on the skin, and on any slippage that could occur between the skin and the test object if the force was insufficient. The signals recorded from the nerve were compared to signals recorded with and without simultaneous application of FNS, while a variety of contact force profiles were applied on the footpad.

Results—In the past year it was shown that: 1) pure sensory nerve information, uncontaminated from stimulation artifacts or electrical activity in the stimulated muscles, can be obtained from implanted nerve cuff electrodes during FNS; 2) the activity recorded from sensory nerves supplying the footpads contains information about the force applied on the skin that can be extracted in real-time using computer-based signal analysis techniques; 3) the activity recorded from sensory nerves supplying the footpads contains reproducible information about the slippage that can occur between the skin and the object when the applied force is insufficient, when the weight

Recent Publications Resulting from This Research

Linear and Nonlinear Approaches to Control of Single Joint Motion by Functional Electrical Stimulation. Durfee W, DiLorenzo D, in Proceedings of the 1990 American Control Conference, 1990. Sliding Mode Control of FNS Knee Joint Motion. Durfee W, DiLorenzo D, in Proceedings of the First World Congress of Biomechanics, 1990.

of the object changes, or when external perturbations to the position of the object occur; and, 4) in addition, a fully implantable connector was developed that permits periodic access to implanted recording or stimulating devices, without permanent passage of wires through the skin, and without any type of telemetry.

Future Plans/Implications—Moment-to-moment information on applied force and slippage, obtained from nerve recordings, is currently being used to control the electrical stimulation of muscles in closed-loop form in anesthetized cats.

The properties and limitations of this closed-loop FNS approach are being assessed with the intended objective of application toward restoration of stance, gait, or grasp in hemiplegic or paraplegic patients, using FNS and obtaining sensory feedback via implanted electrodes.

Recent Publications Resulting from This Research

Obtaining Skin Contact Force Information from Implanted Nerve Cuff Recording Electrodes. Hoffer JA, Haugland M, Li T, in Proceedings of the International Conference of IEEE/EMBS, 11:928-929, 1989. Techniques to Record Spinal Cord, Peripheral Nerve and Muscle Activity in Freely Moving Animals. Hoffer JA, in Neurophysiological Techniques: Applications to Neural Systems. Neuro-Methods, 15:65-145, A.A. Boulton, G.B. Baker, C.H. Vanderwolf (Eds.). Clifton, NJ: Humana Press, 1990. Fully Implanted Transcutaneous Connector for Nerve or Muscle Recording and Stimulation. Haugland M, Hoffer JA, Sinkjaer T, First European Conference on Biomedical Engineering, Nice, 1991.

Patents

Closed-Loop, Implanted-Sensor, Functional Electrical Stimulation System for Partial Restoration of Motor Functions. United States Patent Number 4,750,499, awarded to J.A. Hoffer; Date of Patent: June 14, 1988.

V. Geriatrics

For additional information on topics related to this category see the following Progress Reports: [334], [375], [385], [502], [513], [528], [620].

[154] Interventions to Improve Dressing Behavior in Cognitively Impaired Veterans

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Sponsor: VA Rehabilitation Research and Development Service (Project #E558-RA)

Purpose—The purpose of this study is to examine the difference in dressing assistance that subjects require before and after receiving the clinical intervention of Strategies for Promoting Independence in Dressing (SPID), a set of environmental and interactional behavioral strategies.

Data collection has been completed on two nursing home care units at the John L. McClellan VA Medical Center. Data analysis is complete for one of the two units.

Methodology—A pretest/posttest design was used in which each subject served as his own control. The dependent variable was the level of dressing assistance required, as measured by the Beck Dressing Performance Scale (BDPS). Descriptive data collected on each subject included: 1) the Mini Mental Status Exam (MMSE); 2) the Neurobehavioral Cognitive Status Exam (NCSE); and, 3) the Cognitive Skills for Dressing Assessment (CSDA). The NCSE and the CSDA were used to help determine each subject's remaining cognitive abilities which could be utilized during dressing, and disabilities that precluded the subject from being successful with certain activities.

Nine conveniently selected subjects with dementia in a long-term care unit at a VA Hospital were videotaped during dressing twice for 1 week to desensitize the subjects and caregivers to videotaping. Then, baseline data were collected by videotaping subjects dressing twice a week for 2 weeks. The clinical treatment, SPID, which consists of specific environmental and interactional interventions, was taught to caregivers in a standardized 8-hour training program which included didactic content, role-playing, and return demonstration. Interventions were individualized to each subject's specific abilities and disabilities by a doctorally prepared geropsychiatric nurse in consultation with a neuropsychologist. During

the 6-week treatment period, caregivers were videotaped twice a week during dressing interactions and given weekly feedback and encouragement by the investigators who viewed videotapes weekly to monitor compliance to the intervention protocol. Posttreatment data were collected twice a week for 2 weeks. Data collection videotaping stopped for 3 weeks during which no feedback or encouragement was provided to the caregiver. Follow-up data were collected twice a week for 1 week. Each dressing interaction was rated for the level of caregiver assistance, using the BDPS, by two masters-prepared gerontological nurses who were blind to the time sequence of the videotapes.

Results—The nine subjects, all male veterans, had a primary diagnosis of dementia or Alzheimer's disease. The mean age was 73.89 (sd=7.06) and the mean MMSE score was 6.22 (range 0 to 13).

To determine the mean treatment effects, average scores on the BDPS were determined for the four baseline, four posttreatment, and two follow-up videotapings. Mean BDPS scores showed the level of caregiver assistance decreased from 6.23 (sd=1.88), needing occasional physical guidance, at baseline to 4.67 (sd=1.99), needing repeated verbal prompts, during postintervention and decreased again to 4.25 (sd=2.49) during follow-up observations. The significance of the apparent improvements in the mean BDPS over time was assessed by the paired *t*-test and by Wilcoxon's sign rank test. All comparisons were significant at the 0.05 level or better.

Future Plans/Implications—As more subjects are added to the sample, a time-series analysis will be used to determine when the maximum treatment effect occurs and more stringent statistical tests will be used to determine significance levels of treatment effects. In addition, the

time taken for each dressing interaction is being recorded to allow for time and effort and cost comparisons in the larger sample.

This research provides evidence that caregiver assistance which is carefully matched to the cognitive abilities

and disabilities of the resident can decrease the amount of caregiver assistance needed and that this change can be maintained over time. These findings show great promise for improving the lives of demented older adults by beginning to identify interventions that promote independence.

[155] Detection and Prevention of Loss of Balance in the Elderly: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #E972-PA; Project #E601-RA)

Purpose—The motivation for studying balance in the elderly is to reduce the likelihood of falling, a major cause of morbidity, mortality, and loss of independence in this population. Most balance assessment methods concentrate on the lower body and the relationship of the body's center of mass to the position of the feet. However, control of orientation of the trunk with respect to gravity is a significant factor in maintaining balance. Motion sensors at two locations (i.e., the head and waist) should suffice to detect falls and balance instabilities. Confining observation to the upper body limits information on patterns of gait, but permits trunk motion and head-pointing direction, indicative of attention to direction of movement, to be more readily distinguished.

Our goal is to develop a wearable accelerometric instrument, a "balance orthosis," making it possible to record an individual's movements during everyday activities in a nonlaboratory setting, and identify patterns of movement that accompany loss of balance before a fall actually occurs, alerting the individual of pre-fall behavior, and if necessary, signaling a remote attendant that a fall has taken place. To develop the necessary algorithms for distinguishing harmless from pre-fall motions, we have been testing subjects in the laboratory using elements of standard qualitative balance assessment protocols.

Methodology—In a typical laboratory test, subjects stand barefoot with feet apart and arms held at sides or on hips. Three-axis accelerometers are attached to the front and side of the forehead and waist using Velcro and elastic straps. Sensor outputs are digitally recorded at 20 readings per sec. To record body movement, reflective tape markers are attached to legs, trunk, arms, and head; these are conventionally videotaped and videophotographed at high contrast by a motion analysis system.

Subjects then perform up to 20 tasks, including: 1) standing with eyes open, then closed, for 15 sec; 2) climbing up three steps, turning, then going down three steps; 3) rising from, then sitting in a chair at normal speed; 4) tandem (toe-to-heel) walking as fast as possible for 10 ft; and, 5) walking over 2-, 4-, and 8-inch obstacles placed 3 ft apart.

Results—Elderly subjects had baseline lateral and pitch acceleration but more and higher peaks of 0.01 G or more, increasing to about 0.05 G in the pitch axis with eyes closed. Climbing down stairs produced peaks at the young subject's head (smoothed relative to the waist), but in elderly subjects, peaks were higher and sharper. The finding of amplification of acceleration peaks at the head in the elderly, instead of damping as in the young, is consistent with stiffening of shock-absorbing soft tissues such as intervertebral discs, resulting in transmission of more foot impact up the vertebral column to the head.

Twenty-five elderly (aged 64 to 85 years) and 5 young (24 to 29 years) female subjects were tested during the pilot phase. Data from tests of rising and sitting in a chair were analyzed by deriving the antero-posterior (pitch) angle of the trunk and the difference between this angle and pitch angle of the head. The time average of the angle indicated a shift in orientation of the body relative to vertical, or of the head relative to the body; a high standard deviation indicated unsteadiness in the pitch plane. While young subjects' means varied randomly between trials, elderly subjects' mean head-to-body angles were more often consistently positive or negative (tilting forward or backward). Standard deviation of four elderly subjects sitting down ranged from 0.1 to 0.53; only two were within the same 0.04 to 0.18 range as young subjects. Standard deviation of elderly subjects was

bimodal; eight were similar to young subjects while five ranged from 1.0 to 3.4 during rising, implying that the accelerometric method can distinguish steady from unsteady individuals. Most elderly as well as young subjects were no more unsteady when rising fast than when rising at normal speed; one of eight showed prolonged settling after completing the rise.

The trunk angle relative to vertical during rising from a chair measured by accelerometers at the waist was consistently less than that derived from video image analysis of the line between hip and shoulder markers. The image analysis method could be overestimating the tilt angle, since it cannot distinguish in-plane motion from rotation, while the accelerometers have a subject-specific shift due to body contour; this can probably be corrected by mounting one sensor in back instead of in front.

The stepping-over-blocks test is a new addition to the balance assessment protocol; it was performed by only three subjects. One elderly subject was clearly similar to a young person in antero-posterior head-to-body angle (mean of -0.1 to $+0.15$, SD 0.8 to 1.2), while another had a mean angle of 0.24 to 0.42 radian and SD of 0.24 to 0.34 in three trials. This occurred in an individual with less confidence in her balance, who looked at her feet before stepping over each obstacle.

Future Plans/Implications—An expanded project (#E601-RA) has been approved for VA support. This 3-year project includes: 1) further development of hardware for measuring relative upper-body accelerations; 2) refinement of present software for analyzing data to yield head and torso velocity vectors in real-time; 3) continued laboratory testing of well-defined motion sequences typical of activities of daily living (e.g., talking while walking, reaching for and manipulating objects, walking over curbs and ramps of various heights, and opening doors); 4) continued comparison with simultaneous measurement of displacement by image analysis to verify accuracy of results; 5) expansion of the subject population to include postsurgical patients, whose progress toward independent living is more rapid than that of the fall-prone elderly; 6) expansion to include institutionalized and community-living subjects; 7) integration of accelerometric analysis with other balance diagnosis techniques (one such, the "Equitest," will permit controlled stimulation of falls); and, 8) exploration of reinforcement of fall-avoidance behavior modification using accelerometric feedback.

If successful, the "balance orthosis" project will directly benefit a subset of the fall-prone population who have recognizable pre-fall motion patterns, and indirectly benefit others by improving clinical diagnosis of balance disorders.

[156] Design of a New Toilet: Transfer and Access Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #E951-PA)

Purpose—This study was aimed at collecting data on preferences of disabled people in their daily use of the bathroom. In addition, this study sought to collect data on the approach, access, and transfer from a wheelchair to a toilet fixture by people capable of independent transfer (e.g., paraplegics, low quadriplegics, hemiplegics, victims of polio, amputees, etc.).

Progress—The Rehabilitation Research and Development Center collaborated with the Paralyzed Veterans of America to develop an illustrated survey on the daily use of the bathroom by disabled people. The survey was divided into three categories: use of the toilet, the lavatory, and the bathtub or shower. For each category, readers were asked to comment on their preferred technique of

approach, transfer, and use of the fixture, as well as the type of assisting devices they used. In addition to personal data and type of disability, the survey sought information on the types of modifications the respondents had made in their homes.

Results—The survey was sent to 1800 randomly selected *Paraplegia News* subscribers, and 800 questionnaires were returned—a 45% return rate. The disabilities of persons responding fell into seven categories: quadriplegics, 15%; paraplegics, 45%; multiple sclerosis, 25%; victims of polio, 5%; hemiplegics, 2%; amputees, 1%; other disabilities, 3%. Responses were broken down into the seven disability categories and two age groups.

Fifty-nine years of age and older. 1) Side and lateral transfers to the toilet: quadriplegics, 50%; paraplegics, 37%; multiple sclerosis, 38%; polio victims, 31%; hemiplegics, 20%; amputees, 0%; all other disabilities combined, 20%. 2) Frontal transfer: quadriplegics, 50%; paraplegics, 63%; multiple sclerosis, 62%; polio victims, 79%; hemiplegics, 80%; amputees, 100%; and all other disabilities, 80%.

Less than 59 years old. 1) Side and lateral transfers: quadriplegics, 68%; paraplegics, 48%; multiple sclerosis, 30%; polio, 22%; hemiplegics, 12%; amputees,

16%; all other disabilities combined, 22%. 2) Frontal transfer: quadriplegics, 32%; paraplegics, 52%; multiple sclerosis, 70%; polio, 78%; hemiplegics, 88%; amputees 84%, and 78% of all other disabilities.

Implications—These responses clearly indicate that the traditional technique of transferring from the side is no longer the only method used by disabled people. This is a major finding which justifies rethinking the design of a fixture that was not originally meant to be accessed from a seated position.

[157] Spatial Orientation and Wayfinding in Elderly Persons

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Sponsor: VA Rehabilitation Research and Development Service (Project #E428-RA)

Purpose—A major problem for many elderly persons is that of becoming lost or disoriented while attempting to move about familiar environments while engaged in everyday life activities. In a past survey of 170 nursing homes, it was found that such disorientation characterizes a significant proportion of the nursing home population.

The component processes of wayfinding, particularly among older individuals, are poorly understood. In order to provide a better understanding of the wayfinding abilities of older persons, this 3-year study examined: 1) the ability of older people to find their ways around new and unfamiliar places; 2) changes in wayfinding abilities as people age; and, 3) variances in abilities of older and younger people to find their ways around new and unfamiliar places.

Individuals of two specific age groups were compared in a novel, institutional setting. The comparison included the efficiency of wayfinding, which involves the components of: 1) knowledge of the environment; 2) knowledge of one's location in relation to specific landmarks in the environment; and, 3) retrieval and usage of this information. Factors related to wayfinding competence in the elderly were studied in the residential setting, and included: 1) frequency and range of travel; 2) wandering behavior; and, 3) memory.

Methodology—This study consisted of two parts. Part 1 was a comparison of measures of spatial ability in an unfamiliar building following a brief, controlled exposure to the building with 34 young and middle-aged adults (18-50 years), and 34 older adults (65 and up). Elderly

adults selected for participation were individuals recently admitted to a large retirement center, since one objective of the overall project was to compare their performance on this controlled task with spatial behavior in a more natural setting (i.e., the independent living center). Part 2 was a follow-up of the older adults after their admission to the retirement center. It was designed to examine the relationship between wayfinding competence, as measured in Phase 1, and various measures of adjustment to the nursing home. The subjects' spatial orientation and wayfinding competence in the nursing home and immediate environment, self-confidence in wayfinding, range of travel, wandering behavior, memory and general level of function at 2 weeks, 2 months, 6 months, and each 6-month interval thereafter for a period of 2 years was to be assessed.

Older adults selected for participation were individuals who had recently (within 2 weeks) moved into a large retirement center. Middle-aged adults were selected among recently hired employees and/or volunteers of the VA Medical Center (VAMC), Decatur, GA.

Progress—All of the middle-aged volunteers have been identified and tested in a novel environment at the VAMC, Decatur, GA. Data analysis is well underway with this group.

Nine of the 22 original volunteers in the older group have discontinued participation, having had multiple health problems and been advised by their physicians to stop, or they have died. Longitudinal data is being collected on these 13 participants. Several of these older adults have also been tested in VA's novel environment.

Results—Data are currently being analyzed.

Future Plans/Implications—The results of this study will have implications for understanding the effects of the aging process on spatial orientation and wayfind-

ing. In addition, this study will have applied implications for orienting older adults to new environments. There are hopes that depression and adjustment to new settings will be lessened because of the knowledge gained.

[158] Motivational Devices for Promotion of Aerobic Exercise in the Elderly

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Purpose—The objective of this 2-year project was to evaluate the influence of exercise enhancement devices on the attitude and perception of exertion of young, middle-aged, elderly, and wheelchair-confined subjects. The use of different age groups is intended to ascertain whether preference in environmental conditions during solitary exercise is age-related. However, due to a limited time factor, the young age group was dropped.

Methodology—After completing an initial submaximal exercise test and psychological tests, each of the 60 ambulatory subjects selects either a treadmill or a stationary bicycle upon which to exercise. The wheelchair subjects are limited to a modified exercise roller. The same device is used under all three of the experimental exercise conditions. One of the exercise conditions has the subject interacting with the device in a game-like protocol (i.e., a cartoon-figure walking a dog reflects the physiological and motor reactions of the exercising subjects). The video display is designed to be fun, challenging, and to motivate the user to exercise in his/her target heart rate zone, keeping the user safely within the limit of their exercise prescription. The second condition involves a noninteractive video display of exercise views in pleasant environments (i.e., environment scenery as the camera is moved at a bicycling or running pace). The third condition involves stationary exercise without the use of any motivational devices. The subject's heart rate is only seen by the technician but if the subject exercises

at an intensity above his/her range, the program shuts off and that particular session is terminated.

Progress—All experimental testing has been completed. Data from 58 subjects has been analyzed, with two others in the process of being coded. Preliminary results were submitted for presentation at the 1990 Annual Meeting of the American Association of Cardiovascular and Pulmonary Rehabilitation.

Results—In a preliminary analysis of the data, exercise efficacy was assessed in 58 older, healthy adult subjects (mean age 63.8 years). Effects of condition (Exercise Alone, Exercise plus Video Tape, or Exercise plus Video Game) on perceived level of exertion, mean heart rate during the session, time-in-target heart rate, and total time in the session were studied. A series of one-way analyses of variance with repeated measures and appropriate *post hoc* tests revealed that the time-in-target heart rate and perceived level of exertion were significantly greater in the Exercise plus Video Game condition. We conclude that exercise training efficacy seems enhanced under that condition due to the subject's interaction with the video game.

Future Plans/Implications—A follow-up phone survey 1 year from now will be conducted to see if the subjects are compliant with the exercise prescriptions given to them at the end of the sessions.

[159] Assessment of Age-Related Changes in Visual Spatial Organization

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Sponsor: VA Rehabilitation Research and Development Service (Project #C426-RA)

Purpose—This was a 3-year study of age-related changes in visual function and the judgment of egocentric distance, depth, and apparent size. In the study, visual performance was assessed on 128 normal-sighted individuals from two age groups (20-35 and 55-70 years of age). The participants' performance on a battery of clinical and psychophysical tests of vision (e.g., contrast sensitivity, macular stereopsis, tonic vergence, and near and far acuity) was compared with their judgments of distance, depth, and size in reduced and enhanced cue environments. These data are being used to determine relationships among basic visual function, age, and elements of spatial organization. At the completion of the data analysis (December 1990), a baseline evaluation existed upon which comparisons with other groups (e.g., older, low-vision observers) may be made.

Methodology—All participants in this study were given clinical screenings to exclude the presence of age-related pathology such as glaucoma, cataracts, or macular degeneration. All participants had at least 20/30 near and far acuity (corrected). Upon reporting to the laboratory, each participant was further screened for lateral and vertical phorias, contrast sensitivity, and visual field extent. A computer-driven test of tonic vergence was administered by the Parameter Estimation by Sequential Testing (PEST) protocol. The observers were then presented nonfamiliar ("anomalous") target objects of different physical sizes and requested to make judgments of egocentric distance and size. In some conditions ("dynamic trials"), the observer walked a specific distance toward the object and made the distance and size judgments. A similar format was used with a familiar target object (an "Exit" sign). Distance and target size judgments were also made to 1 × 2 ft targets placed outside the laboratory at 67 ft and 185 ft from the observer and viewed under full cue conditions. A novel test of the judgment of short depth intervals was provided through the repeated presentation of a simulated "staircase" in

which the inter-step separation was randomly varied from 4 to 12 inches. A cross-modal response was elicited by having the observer move a step-like apparatus, by foot, until the separation was judged to be the same as the apparent inter-step separation viewed. Each observer made judgments of the inter-step depth under both unrestricted and restricted (approximately 14 degrees) viewing conditions.

Progress—Data collection incorporating the above methodology was completed in July 1990. Data analysis and preparation of manuscripts is ongoing. The project ended in December 1990.

Results—The results of the "staircase" part of the study are available. Older adult subjects were found to be as able as younger ones in separating their feet by a verbally-specified amount (a "calibration" task done without visual input). Male subjects generally did better at matching the required separations for the larger values. Both young and older subjects did reasonably well in judging the height of stair steps presented visually. A restricted view, however, resulted in less accurate judgments, with older subjects benefiting relatively more by an increase in the viewing aperture. The older subjects showed a significantly greater underestimation of the larger stair steps when a restricted view was used, than when viewing the steps without restriction. The presence of an edge-tape to mark the front of each step had an interactive effect with step size and age, but no major effect.

Future Plans/Implications—This study should establish normative data for future studies which will investigate the effects of age-related pathology upon visual distance, depth, and size perception. Additionally, this study supports other laboratory research concerning the human factors of safety and mobility in architectural environments.

[160] Knowledge-Based System for Selecting Elopement-Control Devices

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Sponsor: VA Rehabilitation Research and Development Service (Project #E586-2RA)

Purpose—In order to provide safer environments for demented patients who wander, this study will develop a knowledge-based system to aid in selecting devices to control elopement in nursing homes. The study will produce a computerized database that uses expert judgments as a basis for matching the most effective types of interventions with facility-specific considerations, including building design, staffing patterns, policy, and patient profiles. The knowledge base is intended for use by administrators and health facility designers to aid them in making more informed decisions about the most appropriate device for a specific facility.

Methodology—This study entails a five-step process to: 1) identify prototypical facility descriptions (including typical building layouts, staffing patterns, institutional policies on wandering, and patient profiles); 2) obtain recommendations from health care and facilities experts on the requirements for elopement control devices; 3) identify products that meet the stated requirements; 4) evaluate the responsiveness of the commercially available devices in meeting the stated requirements; and, 5) create the knowledge-based system.

“Typical” VA and “exemplary” nursing home plans have been obtained in order to identify facilities that represent a variety of layouts of typical VA Nursing Home Care Units, as well as private exemplary facilities (e.g., those that have received design awards or are considered to be precedents for other facilities).

Site visits to a minimum of 15 facilities are being conducted in order to obtain information about the facility in-use. The site visits are being used to obtain information on how the building is used—that is, the interactions among building design, routine activities of occupants, and state and institutional practices. This information is being gathered through group interviews of five to seven staff members who are directly involved in patient care (e.g., primary care staff, social workers, etc.), interviews with nursing home administrators, and tours of the facilities.

In addition, nursing home administrators are asked to provide several types of information: patient demo-

graphics, frequency of elopement incidents, institutional policies regarding different types of wandering, staffing patterns, the type and degree of various wandering behaviors, the number of staff per shift, and routine patterns of activity.

Prototypical nursing home descriptions describing the building design, staffing, patient attributes, institutional policies and wandering problems for each nursing home are being developed. These descriptions will provide the basis of the discussion in the health care/facilities experts workshop.

Expert consultants in gerontology, nursing home administration, geriatric health care, health facilities architects, etc., will be identified to participate in a 3-day workshop.

A Health Care and Facilities Experts Workshop will focus on the prototypical nursing home descriptions as the basis for selecting appropriate interventions to address the problem of elopement.

Input from manufacturers of elopement control devices will be obtained through a review of the device requirements determined by the consultant panelists. Manufacturers will be asked to recommend elopement control device(s) that would meet those requirements, and provide nonproprietary, detailed technical and performance specifications on those products.

Electrical/electronic engineers will review the manufacturers' recommendations in order to determine: 1) if, and to what extent, the devices have the technical capability to meet the requirements; and, 2) whether the devices will function in accordance with the claims of the manufacturers.

Database development will result in a multidimensional matrix of nursing home designs, staffing characteristics, patient profiles, and institutional policies. This will be used to identify solutions that most closely meet the requirements of a specific nursing home.

Progress—Plans of VA and exemplary nursing homes have been analyzed, sites identified, and approximately half of the site visits have been completed.

[161] Environmental and Behavioral Factors in Falls Among the Elderly

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Sponsor: VA Rehabilitation Research and Development Service (Project #E539-RA)

Purpose—The specific aims of this study are to: 1) identify and describe the role of salient environmental and behavioral factors in fall and near-fall events among institutionalized elderly persons; 2) compare the relative accuracy of primary data on fall events (e.g., video records) with postincident self-report data (e.g., fallers' verbal reconstructions) and secondary data (e.g., falls incident reports); and, 3) assess the acceptability of the data collection methodology, from the participants' perspective. The long-term objective of this study is to use research to design and evaluate interventions which help to reduce the occurrence of falls among the elderly.

Methodology—The study is being conducted at the Atlanta Veterans Affairs Medical Center (VAMC) Nursing Home. Current alert residents with a history of falling have been invited to participate in this study. This pool of potential participants will be supplemented over the course of the study with new residents who have a history of falling and current residents who develop a problem with falling. Motion-activated, video technology will be used to record naturally occurring fall and near-fall events. No falls will be induced. Participants' nonfall incidents, matched on intended activity and time of day, will serve as control data. Background information will be obtained on participants' visual, sensory, neurological, and cardiovascular functioning using accepted clinical procedures. In addition, participants' overall health status and current medications will be documented.

For approximately 2 months, video technology will be used to record all activities in participants' rooms, including fall, near-fall, and nonfall events. Following a fall or near-fall, participants will be interviewed to reconstruct the event from their perspective. Fall incident reports (completed by Nursing Home staff) also will be obtained. An exit interview with each participant will

determine participants' attitudes toward the video methodology. Environmental and behavioral factors involved in fall and near-fall events will be coded and statistically analyzed. The role of architectural characteristics will be further examined using floor plan analysis techniques.

Progress—Cables have been installed on both floors of the Nursing Home Care Unit to facilitate installation and relocation of the recording equipment as needed. The motion-based video recording system has been assembled, and technical fine-tuning has been completed to assure that a close-to-comprehensive record of incidents in the recording areas is obtained. The first of approximately nine data collection cycles (up to four rooms with at least one resident with a history of falling per room) has been completed. A systematic procedure for reviewing and editing the raw data video tapes has been developed and implemented. The follow-up procedures to reconstruct incident events and obtain Fall Incident Reports, as well as a systematic process to obtain current medical and background data, have been developed and implemented. The draft codebook, which is needed to transform the video, interview, archival, and sensory/medical data into an analyzable form, is completed and being evaluated.

Results—While an insufficient amount of data has been collected to date to permit any systematic form of analysis, several trends have been observed. First, the resident population of the Care Unit is currently more frail than in the recent past, and the frequency and types of near-falls that have been observed (e.g., frequent dependence on objects to steady balance, loss of balance following apparently minimal deviation from an upright stance) seem consistent with what would be expected. Second, over the first 8-week period of video taping, 35 near-falls and one fall have been observed. These incidents involved four participants.

[162] Systematic Observation of Wandering Behaviors in Older People and Contributing Factors

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Sponsor: VA Rehabilitation Research and Development Service (Project #E402-RA)

Purpose—The purpose of this study was to capture and describe the unique patterns of travel of nursing home residents labeled “wanderers” and to explore the relationships between the expression of these travel patterns and a variety of psychological and nonpsychological factors. The following research questions were addressed in this study: 1) What kinds of travel behaviors constitute wandering activity? 2) How do psychological factors such as dementia and depression affect wandering? 3) Do nonpsychological factors like demography, previous occupational demands, or physical impairments play a role in wandering? 4) Is medication an important contributing factor to wandering? and, 5) What are the risks associated with the expression of wandering travel behaviors?

Methodology—This study used an observational methodology based on video monitoring to capture the travel behaviors of nursing home residents, a portion of which had been identified by nursing staff to be wanderers. Travel behaviors were evaluated by two independent raters using a reliable coding scheme developed for this study. All participants were evaluated with respect to cognitive and emotional status, demography, and medication regimens. Participants were classified as efficient or inefficient travelers based on travel behavior and compared with respect to a variety of factors.

Progress—A total of 30 subjects have completed the study protocol at one site. The coding scheme has been developed and interobserver reliability determined. Results for these 30 subjects have been analyzed and are summarized below.

Results—In general, nursing home residents’ travel was efficient in that routes traveled were relatively direct from one location to another. However, a number of residents also engaged in travel behaviors that were inefficient, including repetitively lapping areas (circuiting) and/or random patterns of movement (meandering). Participants

were categorized into two groups composed of individuals whose travel was always efficient ($n=10$) and those who exhibited either meandering or circuiting at least twice a week ($n=8$). Comparisons between these groups revealed that differences were limited to cognitive factors. No differences were found with regard to demography, physical demands of previous occupations, physical disabilities affecting activities of daily living, or the prescription of psychotropic medication. Although both groups appeared cognitively impaired based on their total Dementia Rating Scale scores, the inefficient travel group was much more profoundly impaired. Impairment of recent memory ability was the most important factor that separated the two groups. A significant but modest temporal association between exiting supervised areas and inefficient travel behaviors (circuiting or meandering) was found, which suggested exhibition of these behaviors was not without some degree of risk for elopement. Finally, the emergence of these behaviors was interpreted to be symptomatic of the later stages of Alzheimer’s disease.

Future Plans/Implications—Replication of the study protocol with 10 more participants from the current study site is now underway. Video taping has been completed for these participants and over half of their events have been coded. Following completion of coding and analyses of these data, the study will continue at another site to increase total sample size to 80 participants. Results to date have shown that wandering activity can be objectively measured using an observational methodology based on video monitoring. In the future, development of a technology to electronically map the travel patterns of the elderly will be explored.

Recent Publications Resulting from This Research

A Systematic Observation of Wandering Behaviors and Psychologic Correlates (Abstract). Martino-Saltzman D, Gerontological Society of America Annual Scientific Meeting, 1989.

[163] Predicting Wayfinding Ability from Laboratory-Based Spatial Tasks

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Sponsor: VA Rehabilitation Research and Development Service (Project #D525-RA)

Purpose—The primary goal of this 3-year study is to ascertain whether measures of microspatial (tabletop tests) abilities are related to wayfinding abilities in macrospace (real world) environments. Relevance of this question to the Department of Veterans Affairs lies in the fact that many disabled veterans, such as those who are elderly or have sensory or cognitive deficits, may experience problems in mobility and spatial cognition. The ability to accurately identify handicapped individuals at risk for disorientation would ultimately facilitate intervention in spatial orientation. Relevance to the Department of Defense lies in the fact that many military activities, such as aviation and troop movement, require good spatial orientation, wayfinding, and map-reading skills in unfamiliar and adverse situations. If measures of "tabletop" or paper-and-pencil spatial abilities correlate moderately or well with large space wayfinding, then it may be possible to use microspatial tasks for screening and selection of military personnel for jobs requiring a high degree of spatial ability.

Methodology—To complete this research, subjects ranging in age from 18 to 35 years will be given a battery of "tabletop" or paper-and-pencil spatial tests from the *Kit of Factor Referenced Cognitive Tests*, (Ekstrom, French, and Harman, 1976) which tap various aspects of this complex behavioral domain (e.g., spatial visualization, memory for spatial information, spatial closure). They will also perform a set of tasks which involve viewing a 5 × 7 ft model town, and responding to questions which tap perspective verification and map verification. Finally,

subjects will walk predetermined routes inside a building, and outside in wooded areas and residential areas. After these walks, subjects will perform tasks which tap general Euclidean orientation, feature recognition, temporospatial ordering of landmarks, map placement of landmarks, and route reversal. Difference in mobility in residential and rural settings is of interest because differences in the familiarity, quantity, and salience of environmental information between city and forest will likely affect wayfinding. Data analysis will involve multiple regression analyses in which measures of macrospace ability serve as the criterion variables and psychometric and experimental tasks serve as predictors.

Progress—Data are currently being collected in this project. Preliminary analyses of data were conducted in the first quarter of FY 1991.

Implications—This study will identify which types of microspatial tasks show a valid and reliable relationship to selected macrospace tasks, and the magnitude of those relationships. It may be possible, for example, to use the findings as a basis for the establishment of norms for spatial behavior across age, and thus help in determining the differential effect of normal aging and sensory or cognitive decline as they affect spatial behavior. It may also be possible to extend this work to the identification of compensatory strategies which can be taught to civilians and military personnel in need of enhanced mobility or wayfinding skills.

[164] Why Don't All Impaired Elderly Fall?

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Purpose—The purpose of this study is to clarify the role of impaired mobility in falls among older people. Mobility function can be described in a hierarchical framework.

Impaired mobility is proposed to be a functional manifestation of losses across the components of postural control. Impaired mobility is proposed to be a necessary

but not sufficient factor in chronic falls. Impairments in psychologic, social and environmental domains also contribute to falls risk.

Methodology—The protocol is designed in three phases. Phase 1 identifies subjects with impaired mobility. Phase 2, an in-home examination, identifies the degree of impaired mobility and screens for contributions from the other three domains. Phase 3 examines the neuromusculoskeletal contributors to postural instability in a laboratory setting. Community-dwelling male veterans aged 70 or older are eligible. Clinical measures include: a progressive mobility skills protocol with established hierarchical properties; a functional reach task; psychologic and cognitive measures; instruments to assess social support; and, a structured environmental assessment based on pathway theory. Laboratory instruments include a motor-driven platform fitted with strain gauges, surface electro-

myography, videocameras and software for motion analysis, and isokinetic dynamometry. Measures include visual functions, analysis of EMG and body segment kinetics in both feedforward and feedback paradigms, peak torque, goniometry, and timed clinical endurance testing. The outcome, falls, is monitored with daily diaries and telephone contacts.

Progress—There are 202 subjects aged 70-104 (median 76) enrolled to date. Based on the mobility skills screen, 94 have been assigned to a low risk category and 108 to a high risk category.

Results—To date, there have been 87 falls in 42 individuals. Seven percent of low risk and 32% of high risk subjects have fallen at least once. Two or more falls have occurred in 1% of low risk and 17% of high risk subjects.

[165] Age-Related Changes in Sensory-Motor Performance

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Purpose—The goal of this research is to achieve an integrated understanding of the changes which occur in sensorimotor performance as healthy people grow older. The data will be used to identify functional differences in elderly individuals who are “at risk for falls,” who have a history of unsteadiness or falling. Alterations in the neural signal processing, muscle strength, joint stiffness, walking, and postural steadiness will be compared in healthy elderly subjects and in elderly persons who are unsteady or who have a history of falls.

Our “template” of sensorimotor performance in healthy aging will also be used to compare healthy elderly subjects with patients with neurologic or orthopedic disease, or lower limb prostheses.

Methodology—We are developing a database of performance measures of healthy aging subjects (ages 45 to 84 years). We are objectively evaluating the neuromusculoskeletal system (myotatic reflexes, joint compliance, muscle strength, simple ankle-joint voluntary movements, somatosensory evoked potentials), and systemic functional integrity (standing balance and gait). We will perform the same measures on elderly community

dwellers and residents of the Geriatric Nursing Unit who are unsteady or who have a history of falling.

Progress—Despite the fact that our healthy aging volunteers are physically active, most have deficits in at least one of our test measures. However, our active healthy aging subjects have fewer sensory-motor deficits than previously described for elderly subjects. Some of our measurements will be useful tools to discriminate “healthy” aging from individuals who are unsteady or at risk for falls. Some of our tests indicate significant differences in all healthy older subjects; these tests will be useful in identifying general risk factors for falls.

Results—In healthy aging subjects, we have identified nine types of deficits in biomechanical, electrophysiologic, neurologic, and functional parameters: absent or delayed reflexes, impaired tandem walking, reduced velocity of gait, altered joint interactions in gait, reduced reaction times, altered joint compliance, muscle weakness, impaired sensation, and frontal release signs. We consider these deficits as risk factors for falling and unsteadiness. We will compare the types, prevalence, incidence, and magnitude of risk factors in older subjects

who do not feel unsteady, with those who feel unsteady or have a history of falls. We have assessed standing balance in Alzheimer's disease (AD) patients who are unsteady and have impaired gait by clinical examination. We have developed a simple, objective method to quantify deviations in balance by determining the fractal dimension "D" of the curve which describes the center of pressure during standing. The mean value of D was significantly different for 11 healthy elderly subjects (1.86 ± 0.33) than for 14 AD patients (1.73 ± 0.18). For the AD group, balance was less impaired with eyes closed than open. Severity of balance impairment correlated significantly with degree of cognitive impairment. We have evaluated the gait of nine unsteady, "frail" elderly nursing home residents. These patients (ages 62 to 100 years), are generally deconditioned, and do not have neurological or orthopedic diseases. For the population, all objective measures of gait (gait cycle duration, percent stance, stride length, velocity, and equivalent cadence) differ from measures for healthy elderly subjects by from 2 to 3 standard deviations. The effect of exercise on these patients is being assessed.

Future Plans—Disorders of balance and stability are among the most significant health problems of the aging population; falls are a major cause of mortality, morbidity, immobility, and premature nursing home placement. Our research demonstrates that a diversity of changes may occur in active, aging persons who do not have neurological or orthopedic diseases. Older persons who feel unsteady may have a number of sensory, motor, or neuro-

logical deficits which put them at risk for falling. We suggest that the aging process and risk factors for unsteadiness are multi-faceted problems. A goal of our comprehensive, multi-dimensional studies is to identify routine tests which clinicians can use to identify and treat patients at risk for falling, and that therapeutic regimes can be developed to prevent, treat, or compensate for deficits which place elderly people at risk for falls.

Recent Publications Resulting from This Research

- Cadence as a Functional Measure of Gait (Abstract). Alba H, Arch Phys Med Rehabil 71:818, 1990.
- Determining the Frequency Content of Gait Kinematic Measurements: Implications for Data Acquisition and Analysis. Myklebust B, Myklebust J, in Proceedings of the Sixth East Coast Clinical Gait Conference, 1990.
- Development of Control in Gait: Proposed Joint and Limb Interactions. Myklebust B, Myklebust J, Prieto T, in Proceedings of the First World Congress on Biomechanics, 1:95, 1990.
- Dimensionality of Postural Steadiness (Abstract). Myklebust J et al., Soc Neurosci Abstr 16:1315, 1990.
- The Frequency Content of Human Gait: Kinematic Sagittal-Plane Measurements (Abstract). Myklebust B et al., Soc Neurosci Abstr 16:1319, 1990.
- Postural Control in Healthy Aging Subjects. Myklebust J, Myklebust B, Hu QT, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 215, 1990.
- A Review of Myotatic Reflexes and the Development of Motor Control and Gait in Infants and Children: A Special Communication. Myklebust B, Phys Ther 70:188-203, 1990.
- Standing Balance Measures in Alzheimer's Disease. Antuono PG, Myklebust BM, Myklebust JB, in Proceedings of the Second International Conference on Alzheimer's Disease and Related Disorders, 1990.
- Strengthening and Aerobic Exercise in Nursing Home Residents (Abstract). Sauvage LR et al., Clin Res 38:819A, 1990.

[166] Seat Angle as a Therapy for Patients with Osteoporosis

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Purpose—Osteoporosis is an age-related disorder characterized by decreased bone mass and increased susceptibility to fractures. Clinical observations indicate that spinal extension reduces the level of pain experienced by the patient. A pilot study has been conducted to investigate the relationship between seat angle and spinal extension in patients with osteoporosis. The hypothesis is that significant extension of the spine can be accomplished in osteoporotic patients by increasing the angle of the seat and thereby increasing anterior pelvic tilt.

Methodology—The subjects for the study consisted of nine female patients diagnosed with osteoporosis. The patients were placed in a Balans chair which had been modified to allow a range of seat angles from 0 to 30 degrees. Reflective markers were placed on the forehead, chin, C7, T6, L1, sacrum, anterior superior iliac spine (ASIS), trochanter, femoral condyle, and seat. A video tracking system was used to record the position of the markers. Three samples were taken at seat angles of 0, 5, 10, 15, 20, 25, and 30 degrees. Segment length and angle

information were determined through software analysis of the video data.

Preliminary Results—Regression of the T6-C7 angle and seat angle and a regression of the angle between the T6-L1 and L1-S segments and seat angle were not statistically significant. However, it is apparent from the data that both spine angles decrease as the seat angle increases. Preliminary analysis supports the stated

hypothesis: the increase of the lordosis and the decrease of kyphosis indicate an increase in spinal extension as the seat angle and anterior pelvic tilt are increased.

Recent Publications Resulting from This Research

The Relationship Between Seat Angle and Spinal Extension in Patients with Osteoporosis. Neth DC et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 105-106, 1990.

[167] Use of Technology to Promote Rehabilitation of Older Persons: Reducing Barriers to Independence

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Disabilities often make it difficult for the older person to function maximally at home; such persons are also at increased risk of injury through accidents. The effective incorporation and use of environmental features are central to the safety and rehabilitation of the older person, i.e., to maintain independence, prevent further disability, reduce family worry, and prevent institutionalization. Although technology has been widely used to solve problems of rehabilitation, this has not been particularly true in geriatric rehabilitation.

This project's ultimate goal is to develop a sub-center on technology within the Rehabilitation Research and Training Center on Aging. Focusing on safety problems in the older disabled persons' homes, a set of critical problems will be identified. Existing commercial products designed to solve such problems will be tested in the home and/or laboratory setting, and modifications and developments of products will be conducted to fill identified problem-technology gaps.

Dissemination activities are an important component of this project. The dissemination activities include the production of a home safety resource notebook, preparation of articles for publication, the development of product utilization workshops, and the presentation of information at conferences concerned with geriatrics, rehabilitation, or human factors.

Progress—This 5-year project is now midway through year three. First, a comprehensive literature base was compiled. Based on a review of this literature, as well as the National Electronic Injury Surveillance System

(NEISS) data, it was decided to focus the project on three major accident categories: falls, burns/scalds, and medication intake errors. The next major goal was to identify a universe of critical in-home safety problems for disabled elderly. This was accomplished by reviewing previous work on safety and the older person, as well as interviewing a sample of 30 health-care professionals whose primary responsibilities include in-home assessments with older persons.

Using the list of identified in-home safety problems, year two of the project focused on identifying existing commercial products which have the potential to alleviate these safety problems for disabled seniors. Using assistive device catalogues, ABLEDATA, and clinical expertise, approximately 200 such products were identified, organized according to the safety problems they address, and placed into a database. This safety-assistive device database will be maintained throughout the project. Next, work began on a "Home Safety Resource Notebook." This book is intended for a wide range of readers (professionals, caregivers, and seniors), and will present the safety problems as well as suggested behavioral and technological solutions from the project. The book attempts to treat safety and technology topics with slightly more depth than previously published such resource guides. It will also provide thorough information as to where the featured products can be obtained. A final draft of the book should be ready early 1991.

Future Plans—The balance of the project will be occupied with hands-on product testing and development.

A sub-selection of the products identified earlier in the project will be brought into our laboratory for evaluation. The parameters to be addressed in this evaluation include the efficacy of the product in solving the environmental, functional, and/or psychological problems related to each accident category. Issues of user-friendliness will also be studied. These data will come from hands-on participa-

tion of disabled seniors in this phase of the project; i.e., they will be in the laboratory helping us evaluate the products. Based on these evaluations, a numerical "product evaluation score" will be obtained. This score is intended to provide a method by which other professionals and lay persons can easily understand our evaluation of each product.

[168] Attitudes Of and Toward Older Persons with a Disability: Their Measurement and Their Role in Rehabilitation

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Supportive attitudes and accurate knowledge of the rehabilitation of older adults with disabilities can go a long way in furthering successful health care. Conversely, negative attitudes and lack of knowledge regarding rehabilitation care of geriatric patients can be detrimental to patient rehabilitation outcomes. The patient's family and physician play a large part in determining the level of the older person's adjustment, level of functioning, health status, and life satisfaction. The attitudes of these three key parties can be crucial and act as either facilitators or inhibitors of the rehabilitation process. For example, attitudes may influence patient motivation, support and assistance given by the family, and patient treatment by the physician. To date no instruments exist that specifically measure attitudes toward older adults with disabilities.

This study is a 5-year project funded to develop psychometrically sound scales that measure attitudes of and toward older persons with a disability, and to investigate geriatric rehabilitation outcomes in relation to attitude patterns among the family, the doctor, and the patient. These findings will highlight which attitudes interfere with which rehabilitation outcomes, and disseminate information on how to reduce these barriers.

Progress—Development of an attitude scale is in its final stages. A final draft of the *Attitudes Toward Older Adults with Disabilities Scale* contains 60 items drawn from existing attitudinal scales, consultation with professionals in gerontology and geriatrics, and consultation with disabled older adults. The scale has attempted to include the three major types of items based on Fishbein and Ajzen's concept of attitudes, which are affective orientation,

attitudinal beliefs, and behavioral intention. The items address content areas of social, psychological, functional, and societal attitudes, and personal reactions toward the disabled older adult. This scale has been distributed to 300 persons ranging in age from 18 to 90 in a local community.

Results—Internal consistency for the five content areas range from 0.50 to 0.84, with an average of 0.70. Significant relationships exist between attitude scores and education and age, with positive attitudes related to higher levels of education ($F=9.63$, $p<0.001$) and decreased age ($F=12.80$, $p<0.001$). Validity studies are planned for the future which will compare attitude scores with a semantic differential measure of attitudes toward disabled older adults, and attitudes of groups identified as having unusually "good" attitudes (i.e., professionals who specialize in geriatrics or gerontology), "neutral" attitudes (the general public), and "bad" attitudes (group not yet identified). Other validation studies are also in the planning stages.

Future Plans/Implications—Once the final version of the scale is complete and validity studies have been done, this scale will be used to test the influence of attitudes upon the rehabilitation process and outcomes of geriatric inpatients. Attitudes of family members, the patient's physician, and the patient him/herself will be explored. It is hoped that understanding the influence and patterns of attitudes toward older disabled adults will help facilitate rehabilitation success and point out where attitude changes are needed. Education regarding disability in old age may be one way to change harmful attitudes. Hopefully, this scale will encourage research

on the impact of attitudes toward the disabled older person and how to reduce the negative ageism that exists toward this group.

Information on the development of the attitude scale was presented at the American Society of Aging Conference in April 1990, in San Francisco.

[169] Late-Life Effects of Early-Life Disability: Comparisons with Age-Matched Controls on Indicators of Physical, Psychological and Social Status

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Many persons with disabilities are now living to later life but experiencing the onset of new medical, psychosocial, and functional problems. Two of the largest such groups are people with post-polio and spinal cord injury (SCI). Post-polio individuals are experiencing primarily fatigue, weakness, pain, and loss of strength. The SCI population is experiencing multiple medical problems which include osteoporosis, renal disease, hypertension, respiratory and cardiovascular problems, and generalized amyloidosis. Although increasingly these problems are described in the clinical literature, to date little systematic research has focused on the long-term consequences of an early life disability. The purpose of this project is to correct this shortcoming by conducting a well-controlled study comparing early-life disabled individuals (post-polio and SCI), age-matched nondisabled, and late-onset disabled persons (such as those with stroke and diabetes).

The objectives of this study fall into two separate categories. First, we will focus on a variety of medical, psychological, and social variables to determine if there are differences between our four subject groups. In this way we can assess to what extent the changes reported are due to aging alone, to duration of disability, or to a com-

bination of factors including life style. Second, we will look more closely at the aging person with an early-life onset disability: 1) to determine if there are gender differences in health and functional changes associated with aging and/or life style; 2) to determine the kinds of services these individuals need in order to continue their independence in the community; and, 3) to gather additional data to test a compensation hypothesis as a major factor in late-life sequelae to early-life onset of disability.

Progress—In the third year of a 5-year study, major activities have focused on subject identification and recruitment, data collection, instrument revisions, and creation of a computerized sample accounting and data management system to track subjects and sub-samples across various stages of data collection. Information is being collected via questionnaires, in-depth interviews, and clinical assessments by a team consisting of a physician, psychologist, physical therapist, and family sociologist. Our achieved sample to date includes 70 post-polios, 21 SCI, and 35 nondisabled. Subject recruitment for the fourth group of late-onset disabled individuals began in Fall 1990. We anticipate completing data collection a year later in the Fall of 1991 with an total sample of 250.

[170] Interdisciplinary Human Development Institute Consortium on Aging and Developmental Disabilities

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Interdisciplinary Human Development Institute (IHDI) cooperates with the Universities of Cincinnati, Akron, Minnesota, Illinois-Chicago, and Indiana University in a consortium effort as the Research and Rehabilitation Training Center on Aging and Developmental Disabilities.

The purposes for the IHDI component are to design, develop, and field-review interagency models for long-term fiscal support of small-scale community living options for older persons with developmental disabilities, and to make projections for training and technical assistance.

Methodology—The research component is based on five goals: 1) develop a value-based planning process to ensure consideration of criteria for quality of life based on maximum continuing personal life choices and social integration for older persons with developmental disabilities; 2) improve fiscal efficiency of programs via interagency funding models that support small-scale community living options for older persons with developmental disabilities; 3) identify effective small-scale community living options that respond to individual need, personal choice, and community integration for older persons with developmental disabilities; 4) develop and disseminate a resource document on interagency planning model(s) that integrates value-based planning processes; effective options for small-scale community living, and fiscally efficient long-term funding to support small-scale community living options for older persons with developmental disabilities; and, 5) design and develop training materials and technical assistance procedures for interagency planning for long-term funding to support small-scale community living options for older persons with developmental disabilities.

Progress/Results—A national survey of state mental retardation/developmental disabilities agencies was completed on March 30, 1990. Forty-seven of 51 surveys were returned. Brief highlights from the surveys are: 1) 19,570 older persons with developmental disabilities are residing

in small-scale community living options—the largest percentage reported was board-and-care homes (18.6%); 2) 1.5% of the older persons were living independently; and, 3) for each older person living in community options with federal funding, 2.5 older persons live in community living options supported by state funding.

The data analysis produced enough information to proceed with the four working papers scheduled for dissemination by September 30, 1990: (a) Volume One Number One: *Results of a National Survey of State Mental Retardation/Developmental Disabilities Agencies Serving Older Persons with Developmental Disabilities*; (b) Volume One Number Two: *Current Fiscal Models for Supporting Small-Scale Community Living Options for Older Persons with Developmental Disabilities*; (c) Volume One Number Three: *Quality of Life Issues for Older Persons with Developmental Disabilities*; and, (d) Volume One Number Four: *Interagency Taskforce Planning for Older Persons with Developmental Disabilities*.

Information and technical assistance on these issues have been provided at the Midwest Congress on Aging in Kansas City, the South Carolina Divisions of Aging and Mental Retardation, the American Association on Mental Retardation Conference in Atlanta, and the Southeastern Region's UAP Conference on Aging and Developmental Disabilities in Atlanta. A monograph is planned for completion by June 30, 1991.

[171] Rehabilitation Research and Training Center Consortium on Aging and Developmental Disabilities

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The Rehabilitation Research and Training Center (RRTC) Consortium on Aging and Developmental Disabilities is committed to improving the community integration of older persons with mental retardation (MR)

and other developmental disabilities (DD) through the combined efforts of a consortium of seven universities (Illinois, Indiana, Kentucky, Minnesota, Wisconsin, Akron, and Cincinnati) in six states.

Progress—The Center's research and training program serves as a national resource for researchers, planners, service providers, and consumers by increasing knowledge about this previously neglected population of older persons with DD, and ensuring availability and utility of this knowledge base to the policy, planning, and service delivery of both generic aging and specialized MR/DD agencies. The current research program includes nine research projects in four areas of concentration: 1) fiscal and program policy analysis; 2) detection of decline; 3) transition reactions and family support; and, 4) collaborative training investigations.

Methodology—Coordinated research efforts are being completed in the respective area of concentration of each of the nine research projects. (Information is available on each of the nine research projects upon request.) At the completion of the third year of this research program (June 1991), the findings of the nine research projects will provide a basis for an integrated research and training program for years four and five. This integrated program will involve both a state-of-the-art research study on improving the functioning of older persons with MR/DD which has the potential of establishing a direction for future research, and a national dissemination plan targeting research, planning, service, and consumer groups. In addition, persons with MR/DD and their family members participate during all phases and at all levels of the RRTC's research and training activities.

Results—Specific research results are not available at this time, but major outcomes have occurred or are projected through national linkages, consumer participation, and implementation of a research and training program. Three groups targeted by the RRTC are: 1) administrators, planners, and policy makers; 2) service providers; and, 3) individuals with developmental disabilities and their families. Some projected outcomes include: deter-

mining future directions for research in aging and DD; developing reliable fiscal/program databases for planning services; recommending future policy that reflects the community integration of older persons with DD; providing technical assistance for networking with generic aging and DD services; identifying prevention strategies for coping with relocation and change for older people with DD; creating models for community-based living arrangements; designing assessment instruments for detecting age-related change; preparing people with DD and their families for life changes; improving the community integration of older persons with DD through accessibility to generic services; and, involving older persons with MR/DD and their family members as advisors and committee members to guide in all phases and at all levels of the research and training program.

Principal investigators and staff of the RRTC have provided the following: internships/practica for 32 students; 118 in-service training sessions; 166 professional presentations; 961 technical assistance contacts; and have disseminated over 52,000 pieces of information on aging and developmental disabilities. In addition, a Clearinghouse on Aging and DD has been established to provide information concerning the community integration of older persons with MR/DD. The Clearinghouse responded to 2,065 requests for information. A quarterly newsletter with a circulation of nearly 6,000, the *A/DD Vantage*, is published to raise awareness of the many and diverse issues related to aging and MR/DD.

Future Plans/Implications—It is the intent of the RRTC Consortium on Aging and DD to improve the quality of life and integration in the community for older persons with MR/DD. The integrated intervention study based upon the research findings of the RRTC, to be piloted by the RRTC in 1992, will serve as a national model to begin accomplishing this goal.

[172] Patterned Urge-Response Toileting for Incontinence

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Sponsor: National Center for Nursing Research, National Institutes of Health

Purpose—The overall purpose of this project was to test the efficacy of a noninvasive, behavioral treatment called Patterned Urge-Response Toileting (PURT) on urge/functional urinary incontinence among nursing home

residents. The specific aims of the project were to test the effect of PURT on: 1) the frequency of urinary incontinent episodes and associated volume of urine among incontinent nursing home patients; 2) the incidence of

complications (e.g., skin irritations and urinary tract infections) among incontinent nursing home patients; 3) the psychosocial well-being of incontinent nursing home patients; 4) the behavioral capabilities of incontinent nursing home patients; 5) the knowledge about urinary incontinence and attitudes of nursing personnel toward caring for incontinent patients; and, 6) facility costs for incontinence care.

Methodology—PURT is an individualized behavioral treatment program for decreasing urge/functional urinary incontinence (UI) among nursing home patients. The treatment strategy consists of a refinement of habit training, but instead of imposing a training schedule on patients, an ambulatory electronic monitoring device is used to obtain the exact timing of voiding occurrences for three consecutive 24-hour days for each patient in the study. The voiding pattern of each patient is precisely identified and translated into an individualized toileting prescription for staff to follow, which reinforces the natural voiding pattern of the patient.

The electronic monitoring device used was the Urinary Incontinence Monitor (UIM), a device which recorded and stored data on the occurrence of incontinence by means of a temperature thermistor when urine at core body temperature was expelled. Data were recorded in minute intervals in real clock time, then dumped directly into a computer for analysis by means of a software program written for this purpose. The device was no larger than 2 × 3 inches with solid state components.

Results—Eighty-eight subjects from four nursing homes completed the 36-week project. The treatment reduced incontinence by an average of 0.9 urinary voiding episodes per day, which was a statistically significant

change with respect to the subjects' baseline and in comparison with the performance of the control group. Incontinence levels declined for one-third of the treatment group by more than 20%. However, compliance rates of the indigenous nursing staff, who carried out the program under the supervision of research staff, were only 70%, which may have dampened the maximum effect of the treatment. The improvement in continence did not significantly affect the incidence of urinary tract infections, skin rash, skin breakdown, or psychosocial status; however, statistical significance was achieved with behavioral capabilities with elimination, achievement/motor skills level, and dependency status.

Direct costs of labor, supplies, and linen were also determined for incontinence and toileting care. Cost savings occurred in linen and supplies, while labor cost actually increased.

Future Plans/Implications—The current standard of UI management in nursing care is to change/toilet patients at the convenience of the staff rather than at times when patients need to void. This is not only time-consuming for staff, embarrassing and disruptive for the incontinent individual, it is also potentially inaccurate by as much as 59 minutes. The UIM is accurate, nonintrusive, and does not require frequent staff attention. (This device is expected to benefit and appeal to nursing homes where the incontinent rate is now over 50%, and among certain people in the community where the rate of incontinence is about 15%.) However, it takes staff longer to toilet patients than to change them after they are wet, which provides little incentive for staff to change their behavior toward more toileting. Thus, the standard of nursing care around UI management must be altered for a strategy such as the one described in this project to be incorporated into nursing practice.

[173] Managing Lower Urinary Tract Dysfunction in Aging Women

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Sponsor: National Center for Nursing Research, National Institutes of Health

Purpose—The goal of this project is to manage lower urinary tract dysfunctions in aging women. Currently, the effect of exercise and biofeedback on stress urinary incontinence (SUI) and mixed (SUI and urge) incontinence, respectively, are under study.

Progress—In earlier research, methods to assess intravaginal pressure developed during voluntary contractions of the pelvic muscles (PM) and a PM exercise protocol were tested. Reproductive-age women in normal health demonstrated significant improvement in intravaginal

pressure after 6 weeks of exercise at home. Reproductive-age women with SUI obtained significant improvement in incontinence and intravaginal pressures after 6 weeks of PM exercise at home. Research on the intensity and duration of PM exercise necessary to significantly increase intravaginal pressure in healthy, aging women was undertaken.

Methodology—A series of 11 custom-fitted intravaginal balloon devices (IVBD) to measure the pressures developed by the PM were used. To monitor abdominal pressure, a 0.25×1×2 cm posterior balloon device (PBD) was fabricated and positioned in the posterior fornix of the vagina. At the baseline assessment, an alginate (Healthco International, Boston, MA) impression of the vagina was obtained; the impression was used to match an IVBD from the series to the subject. The water-filled PBD and IVBD were attached to strain gauge pressure transducers and a dual channel strip-chart recorder. The system was opened to atmospheric pressure and calibrated with a mercury manometer prior to placement of the IVBD and PBD in the vagina. Tracings reflecting pressures developed by the CVM during relaxation and contraction and abdominal pressures were obtained.

The intervention was a graded program (increased every 3 weeks) of regular (3 times per week, every other day) PM exercise at home lasting 12 weeks. The exercise program began with sessions requiring 15 repetitions of a 12-second contraction of the PM. Ten repetitions were added every 3 weeks, resulting in 45 repetitions during the final (fourth) interval. An audio cassette tape recording was provided to guide the exercise sessions.

Analog and digital data were obtained on the IVBD and PBD during 10 contractions representing maximum,

sustained contractions of the PM for 12 seconds and the corresponding abdominal pressure. These data were obtained at baseline and at four exercise levels. Characteristics of the pressure curves analyzed included: 1) maximum pressure (MP10); 2) minimum pressure (MinP10); and, 3) sustained pressure (SP10).

Results/Implications—The sample (N=85) was between 35 and 78 years of age (mean 52.6; SD 10.6). Multivariate analysis of variance showed that there were statistically significant differences among the exercise levels for the variables MP10, MinP10, and SP10. Significant increases in intravaginal pressure occurred after exercise intervals 1, 2, and 3, on each of the three pressure curve variables. Significant improvement did not occur at level four on two study variables. It may be that 35 repetitions per session represents the optimal exercise intensity.

Our results indicate that improvement occurs with exercise intensity at levels lower than that reported in the incontinence literature. Questions about the relationship between the mechanisms of continence and PM exercise merit further investigation. Valuable comparative data on the pressure curves will become available when we complete our study on aging women with SUI.

Recent Publications Resulting from This Research

- The Effect of Circumvaginal Muscle (CVM) Exercise. Dougherty MC et al., *Nurs Res* 38(6):331-335, 1989.
- The Effect of Exercise on the Circumvaginal Muscles in Postpartum Women. Dougherty MC et al., *J Nurse Midwifery* 34:8-14, 1989.
- Stress Urinary Incontinence: Effect of Pelvic Muscle Exercise. Ferguson KL et al., *Obstet Gynecol* 75:671-675, 1990.

[174] Cognitive and Emotional Profile of Neuropsychiatric Disorders

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—A neuropsychological profile was plotted for individuals with Alzheimer's (AD), Huntington's (HD), or Parkinson's (PD) disease. The evaluations extended into memory, learning, and perception, utilizing standard and experimental tasks, and also established normative references for functional changes accompanying the aging processes.

Results/Implications—The results revealed common as well as specific deficits, implicating involvement of different brain structures. Specifically, AD is accompanied by marked deficits in selective attention, episodic memory, and visuospatial disturbances; there were few qualitative differences between demented and age-matched subjects. These data indicate that Alzheimer's

patients may be unable to encode material. AD and HD patients showed pronounced but dissimilar deficits with visuospatial and constructional tasks. The behavioral data extend neuropathologic impressions of degeneration of the frontal striatal system in HD and temporo-parietal, cortical involvement in AD. With PD, performance decrements were less prominent and

many patients continue to function at an unimpaired level; dysfunctioning varied in relation to complexity and executive requirements, which aligned strongly with fronto-striatal changes. Unlike HD, PD patients usually showed fewer behavioral and personality changes; emotional expression was not one of disinhibition.

[175] Alzheimer's Disease and Driving

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Sponsor: *Ontario Ministry of Transportation*

Purpose—This project will investigate whether there are any predictable relations among the severity of intellectual deficits, particularly those seen in Alzheimer's disease, selected neuropsychological tests that are related to driving ability, and the ability to drive a motor vehicle. There are between 240,000 and 288,000 Canadians with Alzheimer's disease (AD). In addition to the widely-known disorders in memory performance, individuals with AD also suffer from losses in other areas of cognition such as attention, reaction time, judgment, and visuo-spatial processing. Thus, there are a large number of Canadians who may be subject to cognitive deficits that can directly impact on their ability to operate a motor vehicle. Physicians in Ontario are required by law to report to the Ministry of Transportation those individuals considered unfit to drive. However, physicians have very little data upon which to base such a report.

Methodology—This study will test actual on-road driving performance as well as a variety of tests of cognitive functioning, visual processing, and reaction time in two groups of participants: individuals from the Toronto

General Hospital Alzheimer's Disease and Related Disorders (ADRD) Clinic who are cognitively impaired/not demented; and a group of control subjects of the same age as those in the patient groups. There will be 24 participants in each group, all currently driving or with valid licenses at the time of their entry into the study. Information also will be gathered by questionnaire regarding driving habits and accident history. These will be filled out by both the patients and their caregivers.

Future Plans—The data will be analyzed to determine whether any of our chosen variables predict actual driving test performance in our patient or control populations. If any predictors are significantly and highly correlated with driving performance, it may be possible for these tests to be used to support a physician's clinical impression of an individual's inability to drive safely.

Recent Publications Resulting from This Research

The Impact of Alzheimer's Disease on Driving Ability: A Review.
Donnelly R, Karlinsky H, J Geriatr Psychiatry Neurol 3:67-72, 1990.

VI. Head Trauma and Stroke

For additional information on topics related to this category see the following Progress Reports: [86], [94], [95], [99], [102], [448], [458], [460], [461], [462], [463], [485], [499].

[176] Computer-Assisted Treatment of Hemi-Inattention in R-CVA Patients

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B610-RA)*

Purpose—This project is designed to evaluate the efficacy of a computer-assisted training program in reducing the accident prone behaviors of R-CVA victims suffering neglect of left space.

Patients with strokes involving the right hemisphere (R-CVA) have more accidents than all other rehabilitation patients. Our previous work revealed that R-CVA patients with hemi-inattention (i.e., neglect, hemispatial neglect) to left space were more likely to have accidents than either our control subjects (including a group of L-CVAs) or R-CVA stroke victims without hemi-inattention. We also observed that falls during transfers and wheelchair navigation were the most common types of accidents reported for our hemi-inattending R-CVAs.

Methodology—We plan to develop a technique to train R-CVA subjects with hemi-inattention to compensate for hemi-inattention-related problems during simulated high accident risk activities (i.e., wheelchair propulsion, transfers) and evaluate the impact of training on incident reports, ratings of rehabilitation staff, and progress of the subjects during rehabilitation therapies. We also plan to assess the generalization of training to other neuropsychological measures and to a wheelchair obstacle course that we previously developed.

Our training will be initiated within the first 2 days of the subjects' admission to the rehabilitation service in order to maximize its impact on other rehabilitation

activities. The results of training will be compared with a control group which receives training to improve attention, but not to improve scanning or other skills deficient in the hemi-inattentive patient. We will train the experimental subjects to sit at true vertical, systematically scan into left space, and scan while performing computer simulations of risky activities, including propelling a wheelchair through a cluttered hallway, and parking a wheelchair for transferring to a bed. Computer simulation will be used so that training can begin even if the subject does not have the physical ability to transfer or drive a wheelchair initially. Most of our subjects will be wheelchair-bound at the beginning of therapy; however, some of these subjects will be ambulatory with or without assistive devices by discharge. Our experience is that training hemi-inattentive subjects to scan during wheelchair movement generalizes to scanning during walking; hence, we believe that our training will be beneficial even if the subject is ambulatory soon after admission. Our specific objectives are: 1) to investigate if training hemi-inattentive subjects to scan will reduce their accident proneness as indicated by ratings of rehabilitation staff and incident reports; 2) to investigate if training using computer simulation facilitates skill mastery on actual wheelchair mobility and transfers; and, 3) to investigate the degree of generalization of training to neuropsychological tests and to our wheelchair obstacle course.

[177] Hemi-Neglect Syndrome: Visual Scanning and Reading Skills Retraining

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Sponsor: VA Rehabilitation Research and Development Service (Project #C552-RA)

Purpose—Patients with left hemi-neglect after right hemisphere stroke frequently receive perceptual or cognitive retraining as outpatients, after discharge from inpatient rehabilitation programs. In anticipation of conducting a controlled clinical trial of outpatient cognitive retraining, we studied the course of visual left hemi-neglect in patients who received no treatment beyond the standard inpatient rehabilitation during acute recovery.

Methodology/Progress—To date, we have tested 52 right hemisphere stroke patients (age range = 42 to 83; mean = 66.2 years) in the hospital within 4 weeks of the stroke, using confrontation testing and six paper-and-pencil tasks. Confrontation testing involved both unilateral and simultaneous bilateral visual stimulation. Paper-and-pencil tasks were: line crossing, line bisection, letter cancellation, the position preference index for the Raven's Colored Progressive Matrices Test, left-margin-indented paragraph reading, and drawing or copying pictures and designs. Our criterion for neglect was evidence of neglect on two or more of the six paper-and-pencil tasks. Subjects were retested 2 months, 3 months, and 6 months post-stroke if, and only if, they had met this criterion on the previous test session.

Thirty-six patients (69%) met the criterion for visual left hemi-neglect at initial testing. Eleven of these patients became unavailable for further study, and one has not yet been retested. Of the 24 who were tested, 15 met the criterion for neglect at 2 months (62.5%). Of these 15, 2 became unavailable, and 2 others have not yet been retested. Of the 11 who were tested, 7 met the criterion for neglect at 4 months (63.6%). Of these 7, 2 became unavailable, and one has not yet been retested. Of the 4 who were tested, all continued to meet the criterion for neglect at 6 months (100%).

The 15 subjects who dropped out of the study had become unavailable for the following reasons: 7 transferred to nursing homes, 3 moved away from the area,

4 died, and one refused to participate. On each test occasion, these subjects were similar in severity of neglect to the subjects who remained in the study; therefore, we estimated prevalence of persistent neglect among the 36 subjects who showed it initially using figures prorated from the rate of neglect among those actually tested on each occasion. We estimate that approximately 40% of those who initially met the criterion for neglect would continue to meet the criterion 6 months later, or that 60% would recover without outpatient treatment. These data suggest that much of the improvement described in the rehabilitation literature can be attributed to spontaneous recovery of function. When we have completed data collection on all subjects, we will use more sophisticated statistical techniques to estimate the rate of recovery from neglect.

We also obtained suggestive evidence that confrontation testing with simultaneous stimuli to both hemi-fields was more sensitive to hemi-neglect than were the paper-and-pencil measures. It may be that hemi-inattention deficits during parallel information processing tasks persist after deficits in serial information processing tasks have been resolved.

We are currently analyzing the data to identify early predictors of persistent neglect, to determine the relative sensitivity of various measures of neglect, and to evaluate the possibility of "confound" with educational level.

Future Plans—During the next year, we will address the following questions: 1) Is perceptual retraining effective in ameliorating the perceptual deficits in patients who continue to demonstrate hemi-neglect on paper-and-pencil tests one year post-stroke? 2) Is it effective in reducing the prevalence of persistent neglect in high-risk patients? 3) What proportion of patients with right hemisphere stroke manifest suppression during bilateral stimulation one year post-stroke? and, 4) What are the mechanisms underlying suppression during bilateral stimulation?

[178] Expanding Loose Training Alternatives with Response Elaboration Training

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Sponsor: VA Rehabilitation Research and Development Service (Project #C384-RA)

Purpose—The primary purpose of this proposal is to develop and evaluate computerized versions of an aphasia treatment program (Response Elaboration Training [RET]) so that we can conduct controlled evaluations of stimulus and response parameters that affect generalization.

The following experimental questions will be investigated: What is the relative efficacy of RET and a didactic aphasia treatment program for facilitating an increase in the number of content words and novel content words produced by mildly to moderately impaired aphasic patients?

Will improvements generalize to and be maintained on: 1) untrained stimuli; 2) standard probes conducted with familiar individuals and untrained settings; 3) spontaneous speech; and, 4) standardized language measures?

What is the relative effectiveness of RET's minimal context presentation as compared to a contextual-animated stimulus presentation for facilitating generalized improvements in the verbal elaboration abilities of aphasic patients?

Does an RET format that restricts stimuli and patient response options to a controlled set of semantic relations (e.g., agent, action, etc.) facilitate generalized improvements in verbal elaboration abilities for aphasic patients?

Progress—Previous results have demonstrated that RET facilitates an increase in the amount and variety of informational content (e.g., content words) produced by aphasic patients. A moderate degree of generalization to stimuli, settings, and individuals has also occurred.

Extensive time series data have been collected and analyzed for 15 aphasic patients and social validation data have been collected for 10 matched normals. In an attempt to further examine the efficacy of RET, intervention was initiated to facilitate acquisition of an elaborated drawing system as a means of functional communication for nonverbal, aphasic-apraxic subjects. Subjects acquired the ability to spontaneously produce elaborate drawings in response to training stimuli and functional generalization probes.

Methodology—The effectiveness and generality of RET is being examined using single case experimental design. Variations of RET have served as the primary independent

variables and measures of informational content have been used as the primary dependent variables. The computerized variations of the RET protocol allow us to systematically alter stimulus parameters (e.g., context, auditory input, etc.), and response options (e.g., limited versus extensive choices).

Preliminary Results—For the present project, we have developed computerized RET animated treatment programs. The programs incorporate semiautomatic data collection for response accuracy and reaction time for patients' ability to name the treatment stimuli. Pilot data are being collected while the programs are being refined.

The results from four subjects provide preliminary data on the relative efficacy of RET and didactic aphasia programs. Across subjects, RET facilitates a greater amount of content than convergent, didactic programs for three of four sets of training items. Results of qualitative analysis of novel content also provide data supporting the relative benefits of RET in encouraging response variety. Maintenance of treatment effects is relatively equivalent for the two treatment types.

Future Plans/Implications—Computer analogues of RET will enhance our ability to manipulate stimulus and response parameters, permit examination of the effect of parameter changes on generalization, and facilitate comparisons of RET and traditional didactic aphasia treatment programs. In addition, computerization of the programs will facilitate the development and testing of RET treatment options for a wide range of aphasic patients and clinical problems. Future research will also examine the effect of "cognitive styles" of subjects on generalization and determine if targeting response variety and flexibility as a goal of intervention is more powerful than providing an opportunity for flexible responding.

Recent Publications Resulting from This Research

Aphasia Complicated by Severe Visual Deficits. Kearns KP, Yedor K, in *Difficult Diagnoses in Adult Communication Disorders*, 101-113, N. Helm-Estabrooks, J. Aten (Eds.). Boston: College-Hill Press, Inc., 1989.

Methodologies for Studying Generalization. Kearns K, in Generalization Strategies in the Treatment of Communication Disorders, 13-30, J. Spradlin, L.V. McReynolds (Eds.). Toronto: B.C. Decker, Inc., 1989.

Broca's Aphasia. Kearns KP, in Aphasia and Related Neurogenic Language Disorders, 1-37, L.L. LaPointe (Ed.). New York: Thieme Medical Publishers, Inc., 1990.

An Alternating Treatments Comparison of Loose Training and A Convergent Treatment Strategy. Kearns KP, Yedor K, in Clinical Aphasiology. T.E. Prescott (Ed.). San Diego: College-Hill Press, Inc. (in press).

A Qualitative Analysis of Response Elaboration Training Effects. Gaddie A, Kearns KP, Yedor K, Clinical Aphasiology. San Diego: College-Hill Press, Inc. (in press).

[179] Demonstrating the Efficacy of Memory Training

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Sponsor: VA Rehabilitation Research and Development Service (Project #F471-RA)

Purpose—This project is divided into two components, one involving development of a prosthetic memory device for individuals with severe organic amnesia, and the other for development of memory training computer-based instruction for individuals with milder forms of neurologically caused loss of ability to remember.

The specific purpose of the first component is to design, construct, and field-test a prosthetic memory device. The device will be programmable and portable, and will contain information regarding orientation, safety, and various activities of daily living (ADLs). The device is meant for patients with severe amnesia who have little if any recall of recent events. The subjects for the field-testing will be patients with organic amnesic disorder (Korsakoff's syndrome). The field trials will involve training these patients to use the device, and evaluating its utilization in daily living situations.

The second component involves development and testing of a series of training methods for improvement of memory. The three methods to be tested involve recall of lengthy lists of information, learning the names of new acquaintances, and recalling tasks. The methods will be computer-based and will largely involve imagery as a mnemonic aid. Subjects will be individuals with histories of closed head injury resulting in persistent amnesia.

Progress—The program has only recently been funded and initiated. The first year of its 3-year plan is devoted to development of instrumentation and software. These activities are in progress, and several preliminary programs have been written. "Mock-ups" of the prosthesis have been produced.

Methodology—The prosthesis will be developed based upon concepts derived from cognitive theory. The design of the instrument, its keyboard, its capability of analyz-

ing input and synthesizing output, and the manner in which the information is organized will be compatible with such theory and with what is known about the neuropsychology of patients with amnesia. The steps in the development process are: 1) design and synthesis of a prototype; 2) field trials with expert consultants and normal individuals for "debugging" purposes; and, 3) modifications and clinical trials with patients. There are two parts to this process, one to see if we can teach patients to remember to use the device, and the other to evaluate the extent of its use in natural environments.

The programs for the head-injury subjects are being written for a personal computer. They are based upon previous studies done in our laboratory, partly in non-computerized versions and partly on a newly designed program. Following preparation of the necessary materials, trials will commence with head-injured patients who are having persistent memory difficulties. Following a pretraining assessment, the patients are scheduled for a number of training sessions followed by a posttraining evaluation. There are three criteria for success: improvement during the course of the training, improvement on the posttraining evaluation (which utilizes different materials from those used in the training), and application of the training to ADLs in natural environments. The latter criterion will be accomplished through the application of functional assessments done by the trainees themselves and informants.

Future Plans/Implications—Data collection is planned for late in the second year and during the third year of the project. It would be premature to speculate on implications in the absence of data. However, if the prosthesis development is successful, it may be useful to substantially larger populations of individuals with memory problems, notably individuals with the dementing illnesses of old age.

[180] Effects of Thermal Stimulation on Dysphagia After Stroke

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Sponsor: VA Rehabilitation Research and Development Service (Project #C485-RA)

Purpose—This project was designed to measure the effects of thermal stimulation on impaired swallowing following multiple strokes.

Methodology—Medically stable patients with clinical and imaging evidence of multiple cerebral vascular accidents (CVAs) and delay in the initiation of the pharyngeal response during liquid swallows, as confirmed by videofluoroscopy, were enrolled in this study. We used a modified withdrawal design with matched-subject pairs and replication across 20 subjects. After baseline neurologic and swallowing examinations, subjects were randomly assigned to either an ABAB or BABA pattern. "A" refers to a 5-day no-thermal stimulation phase. "B" refers to a 5-day thermal stimulation phase. Follow-up testing was done one month after subjects were discharged from the study.

Videofluoroscopic data were analyzed traditionally, and with a visual image processing program (Swallowing/Speech Interactive Image Processing Program (SIP). Inter- and intrajudge reliability were determined, and the clinical significance of changes in dependent variables were established by visual inspection of data displays.

Results—Twenty subjects have completed the experimental protocol. Data from the first seven subjects have been analyzed. Two of three judges agree that two of these seven subjects demonstrated decreased "duration of stage transition" with no change in aspiration or penetration. Overall, the data from all seven subjects fail to provide strong evidence that alternating patterns of thermal stimulation/no-thermal stimulation improve dysphagia following multiple strokes. Multiple replications are needed, and data from the next 13 subjects are being analyzed.

[181] An Interactive Computer Program to Assess and Facilitate Cognitive Function in Head-Injured Young People

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Sponsor: Easter Seal Research Institute of Ontario; Apple Canada Ltd.; Hospital for Sick Children Foundation

Purpose—Our purpose was to develop and evaluate a microcomputer-based program for assessing and training language skills in cognitively impaired young people. Specific objectives include: 1) developing an interactive computer program for the assessment and remediation of cognitive-related language deficits in head-injured patients; and, 2) evaluating the effectiveness of this program for remediating the skill areas of attention, comprehension, memory and word retrieval, organization, and reasoning/problem-solving.

Methodology—Software was developed based on an "adventure-type" format. It incorporates the challenge, fantasy, and curiosity elements considered essential for motivated instruction. The software was developed on the Macintosh in HyperCard and utilized scanned artwork, animation, sound and voice output, and voice

input, using the Voice Navigator speech recognition system.

The program consists of two packages: a screening module, and a remediation module. The screening module was designed to provide an admission criteria for the program, and measure the progress (test/retest) achieved through the remediation program. The results are collected in a data file which includes information on whether the response is correct/incorrect, type of response given, number of cues required for task completion, response time per task, and the total time taken to complete the entire module. The response time information added to the quantitative results, and provides insight into the efficiency of cognitive processing.

There are four linked remediation modules: Shipwreck (attention); Fantasy (reasoning/problem-solving); Poser (comprehension/organization); and Cave-In

(memory/word retrieval). Each module focuses primarily on one skill area, although several tasks require the integration of more than one skill. Although the story line differs, the tasks from the remediation modules were designed to complement those in the assessment module. Each task has a database which contains five equivalent problems at three levels of difficulty. This means that no two games are alike, as a different task is presented in succeeding games. Clinical input was used to determine the appropriate difficulty level for each student through the initial set-up menu options. Similar data was collected as in the screening module.

During the second year of the project, the program was to be pilot-tested with adolescents who are recovering from closed head injury accidents. An A, A', B within-subject design was employed so that subjects were their own controls. A standardized assessment battery was administered to establish a baseline measure. The battery was readministered 12 weeks later to measure the extent of spontaneous recovery. Results from the standardized assessment battery were compared with those obtained from the screening module of the software. A 12-week remediation program followed. Upon completion of the remediation program, a third test session was employed to evaluate the effectiveness of the training.

Results—The software was evaluated with three closed head-injured adolescents who were between 4-6 months

postinjury. Subject rankings were obtained from the screening module and compared to the standardized assessment battery. Rankings for subjects were identical, indicating that the program has preliminary face validity. Subjects' initial screening assessment results ranged from 25 to 55% correct, which indicates that task difficulty is appropriate, showing neither floor or ceiling effects. Responses were designed to minimize correct choices made by chance selection.

All three subjects reported that the program was both interesting and challenging. Preliminary results indicate that the remediation program was effective when validated by the standardized tests. One of the most sensitive indicators of recovery was processing time. The screening module demonstrated that processing time had decreased substantially following the computer-based remediation.

Future Plans—A future study with larger numbers of adolescents who have had head injuries is planned to assist with further development of the program.

Recent Publications Resulting from This Research

An Interactive Computer Program to Assess and Facilitate Cognitive Function in Young People with Head-Injuries. Johnson PC, Thomas-Stonell N, in Proceedings of the 3rd Annual Conference on Cognitive Rehabilitation, Clearwater, FL, 454, 1989.
Computer-Based Assessment and Training of Cognitive Skills in Young People with Head-Injuries. Johnson P et al., Minds in Motion (in press).

[182] Substance Abuse Prevention Programming for Patients Incurring Traumatic Injury

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Sponsor: J.M. Foundation

Purpose—A training program for rehabilitation staff on substance abuse prevention will be established as a service to the Rehabilitation Institute of Chicago's traumatic brain injury (TBI) and spinal cord injury (SCI) program, and curricula will be developed for dissemination to other rehabilitation programs. With the assistance of the Illinois Prevention Resource Center,

a non-profit, state-funded alcohol and drug abuse prevention center, this program will develop staff training materials regarding substance abuse prevention services to patients. These services will include curriculum development, patient and family education, staff training, and information dissemination to other care providers.

[183] Quantification of Motor Coordination of the Lower Limb in Normal and Hemiparetic Subjects

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Sponsor: Medical Research Council of Canada; Fonds de la Recherche en Santé du Québec; Department of Health and Welfare, Canada

Purpose—A dynamometer measuring static torques exerted simultaneously in different planes of motion at the hip and at the knee (flexion/extension, abduction/adduction, internal/external rotation, and flexion/extension respectively) was developed. To date, we have used this apparatus in a task-control situation with 22 normal subjects and 14 hemiparetic subjects to quantify and compare torque and muscle activation patterns occurring at the lower extremity.

Methodology—Subjects are seated with their lower limbs secured to two dynamometers. Strain gauges on the dynamometers are interfaced with a desktop computer used to calculate torque in real-time and to collect data. A video monitor is used to display the direction and magnitude of the subject's effort. During the experiment, hemiparetic subjects are asked to successively perform specific efforts (flexion and extension of the hip and the knee), and combined efforts (flexion/abduction, flexion/adduction, extension/abduction, and extension/adduction of the hip with or without feedback regarding torques in internal/external rotation of the hip) at approximately 2.5, 5, 10 and 15% of their maximal voluntary contraction (MVC). For normal subjects, efforts were exerted at 5, 10, 15 and 30% of the MVC. Associated torque at the hip and knee joints were measured during each effort. Electromyographic activities in different muscles of the lower limb (vastus lateralis, rectus femoris, biceps femoris, gracilis, gluteus medius, gluteus maximus, tibialis anterior, and soleus) were recorded concurrently with surface electrodes. In addition, motor and functional performances of hemiparetic subjects were evaluated using different clinical tests.

Progress—The directional specificity of muscle activation was unchanged in the hemiparetic lower limb as compared to normals. However, the level of electromyographic activity of some muscle groups (e.g., erectus femoris), was greater in the hemiparetic subjects. These results differ with the changes observed in directional specificity reported for paretic muscles of the upper limb, suggesting that weakness tends to be more pronounced in the lower limbs of hemiparetic subjects.

Future Plans—The apparatus developed can now be used in different electromyographic, biomechanical, and clinical studies. Eventually, it will be possible to evaluate the described methodology as an evaluation tool or as a treatment modality in clinical studies of stroke patients.

Recent Publications Resulting from This Research

- Abnormal Patterns of Elbow Muscle Activation in Hemiparetic Subjects. Bourbonnais D et al., *Brain* 112:85-102, 1989.
- Ipsilateral Associated Torques Measured During Static Effort at a Single Joint of the Lower Limb in Normal Subjects (Abstract). Bourbonnais D et al., presented at the Annual Meeting of the Society for Neuroscience, 1989.
- A Reliability and Validity Study of a Multi-Directional Dynamometer (Abstract). Gauthier J et al., presented at the 6th Biennial Conference of the Canadian Society for Biomechanics, 1989.
- Quantification of Electromyographic Activities Using Circular Statistics (Abstract). Bourbonnais D et al., presented at the Annual Meeting of the Society for Neuroscience, 1990.
- A Dynamometer Measuring Torques Exerted Statically at the Hip and Knee (Abstract). Bourbonnais D et al., presented at the 13th Annual Meeting of the American Society for Biomechanics (in press).

[184] Pediatric Trauma Registry

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The National Pediatric Trauma Registry (NPTR) is a multi-institutional database managed by the Department of Rehabilitation Medicine at Tufts/New England Medical Center in Boston. The NPTR's emphasis is on how circumstances of traumatic events and acute management of the injured patient affect resulting morbidity and mortality.

Progress—With the support of the American Pediatric Surgical Association Trauma Committee, 53 national centers for pediatric trauma care participate in the data collection effort. Phase 1 (1985-1988) of the PTR contains over 14,000 cases. Phase 2 (October 1988 to present) currently contains over 9,000 cases. By merging Phase 1 and Phase 2 databanks, the project is in charge of one of the most extensive data collection efforts on pediatric injuries in the country. The yearly rate of accumulation is in the order of 6,000 to 7,000 cases, and is expected to increase with the increased demand for participation.

This database allows conduction of several studies designed to evaluate the efficacy of medical and rehabilitative intervention while also accumulating information needed to develop injury prevention programs and activities. The findings from these studies are used to recommend clinical strategies for health professionals and to provide information to policy makers and organizations advocating injury prevention.

Methodology—All injuries to children up to 20 years of age that are traffic-related (i.e., motor vehicle, pedestrian, bicycle, motorcycle, and all-terrain-vehicle), gun-related, caused by falls, stabbing, beating, child abuse, etc., that are treated at the 53 participating institutions are included

in the Registry with the following exceptions: 1) children pronounced dead at the scene, since they are brought directly to the morgue; and, 2) children seen in the emergency room and treated thereafter on an out-patient basis.

The NPTR data collection form is completed by a Trauma Coordinator at the participating institution. These forms are then forwarded to the Department of Rehabilitation Medicine at Tufts/New England Medical Center for coding, verification, and data entry.

Results—Twice a year, in April and October, the Registry generates statistical and graphical reports about the entire data collection, and about data contributed by each institution, for the participants and other interested professionals. Retrieval of information and statistical analyses are also performed upon request.

Falls are the single most common cause of injury in children. However, when combined, traffic-related injuries are the most common cause of injury, especially in the 16-20 year age group.

Recent Publications Resulting from This Research

Inter-Rater Reliability of the Injury Severity Score as Applied to the Pediatric Trauma Patient. Tepas JJ et al., Proceedings of the American Association for the Advancement of Automotive Medicine, 1989.

National Pediatric Trauma Registry. Tepas JJ et al., J Pediatr Surg 24(1), 1989.

Mortality of Head Injury: The Pediatric Perspective. Tepas JJ et al., J Pediatr Surg 25(1), 1990.

Utilization of Inpatient Rehabilitation Services Among Traumatically Injured Children Discharged from Pediatric Trauma Centers. Osberg S, DiScala C, Gans B, Am J Phys Med Rehabil 69(2):67-72, 1990.

[185] Trauma Center Impact on the Disability Outcomes of Brain and Spinal Cord Injured Survivors

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This study examines the extent to which trauma centers are altering the severity and prevalence of disability from traumatic brain and spinal cord injury, and how these changes affect the need for medical rehabilitation and various long-term care services. The study involves about 400 traumatic injury survivors from three level-1 trauma centers, located at the Washington Hospital Center in Washington, DC; the University of California, San Diego; and the University of California, Davis, in Sacramento.

The study will: 1) determine how the probability of survival has changed over time; 2) ascertain the long-term outcomes (up to 5 years) of trauma center survivors; 3) determine the extent of rehabilitation utilization; and, 4) evaluate how injury acuity (e.g., as measured by the Revised Trauma Score) relates to long-term outcome (e.g., as measured by various components of the Sickness Impact Profile).

Methodology—In this study, patients in three major trauma centers who experienced serious head and spinal cord injury during the period 1984-1988 were mailed questionnaires which solicited information on their physical status, rehabilitation experience, and general outcomes since their injury. These data have been combined with trauma data for each patient from the Major Trauma Outcome Study (MTOS), a multi-institutional trauma database sponsored by the American College of Surgeons. Combining these two data sources for the same patients

enables linking trauma acuity data with long-term outcome data for each patient.

Progress—To date, approximately 1,542 letters were mailed to potential respondents. Of this number, 466 persons consented to participate in the study. Questionnaires were mailed to these persons, and 376 questionnaires have been returned to date. Data from the questionnaires have been entered into the study database, and the process of merging questionnaire data and data from MTOS is ongoing. The data-merging process was completed during the Fall of 1990.

Future Plans—The data will be analyzed, focusing on the interrelationship between injury severity, use of rehabilitation services, and functional outcome. This analysis will include an assessment of how injury severity and the receipt of rehabilitation services affect long-term outcomes. The study will also investigate the ability of three injury severity measures (the revised trauma score, the injury severity score, and the trauma score) to predict receipt of rehabilitation, and to predict functional outcome.

Implications—The results of this study will have implications for: 1) knowing how injury severity maps into long-term functional status; 2) identifying appropriate candidates for rehabilitation; and, 3) understanding the impact of trauma care on the need for rehabilitation and other long-term care services.

[186] Studies of Spasticity in Brain Injured Patients

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose/Methodology—The goal of the proposed grant is to objectively test the effectiveness of intrathecal baclofen for spasticity. Patients with spasticity that significantly interferes with motor function or causes painful spasms will be screened with injections of intrathecal baclofen. If they respond, a programmable drug pump

will be implanted to give the medicine chronically. The dose levels needed to control painful spasms, clonus, and rigidity will be determined. Voluntary control, if present, will be tested in the Motor Control Laboratory. Once the optimal dosage has been selected, the patient will receive the drug continuously. Quantitative studies of motor

function, as well as activities of daily living, will be assessed at regular intervals. The prospective study will provide information about the long-term efficacy, as well as the risks of the procedure.

A secondary goal will be to relate decreases in rigidity, hyperactive reflexes, and clonus to voluntary

control. The basic question is whether a reduction in the signs of spasticity necessarily means that voluntary control will improve. If voluntary control does improve, what signs are most predictive, and can these measurements be used to select patients who will respond best to treatment?

[187] Functional Recovery After Focal Cortical Injury (Monkeys)

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—Using recently described quantitative techniques, we documented severe metabolic brain dysfunction far distant from surgically placed lesions in the association cortex of monkeys. Two (frontal and parietal) hemisensory neglect syndromes were documented using behavioral testing. Symptoms correlated in time with metabolic anatomically intact foci of glucose hypometabolism, not structural damage *per se*. Further, neglect animals' behavioral data point to moment-to-moment neural activity changes related to conditions of stimulus presentation. A definitive explanation for neglect symptoms is thus offered for the first time.

Methodology—We propose to further test and expand our original findings using methods previously validated in this laboratory, including: 1) ^{14}C -2-deoxyglucose autoradiography (2DG) to determine quantitative local cerebral glucose utilization (LGU), as an indicator of regional neural activity; 2) operative unilateral lesions that reproducibly induce neglect and other symptoms; and, 3) quantitative behavioral measures of neglect symptoms and their recovery. We will add computer-assisted densitometry and image analysis to improve accuracy of

the LGU measure and computer control of behavioral tests to allow a measurement of orienting efficiency. These methods will be used in experiments to: 1) vary neglect symptoms *vis-a-vis* distant metabolic dysfunction in frontal and parietal animals (e.g., neglect animals infused with 2DG while performing symmetrical motor activity will be sacrificed and the distribution of label compared with the distribution in previously studied nonperforming operated animals); and, 2) determine if other operative lesions outside frontal and parietal association cortex are accompanied by distant metabolic effects and if there are behavioral changes that correlate with them (e.g., we will make unilateral superior colliculus (SC) lesions, and sacrifice with 2DG acutely, and after spontaneous recovery in resting alert monkeys).

Implications—These primate model studies will advance understanding of the distant metabolic effects of focal cerebral damage, and will provide direct correlates for diagnosis and management of human stroke patients, in whom recovery is often impeded by neglect and other higher cortical function deficits.

[188] Cognitive-Linguistic Mechanisms in Writing Disorders

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—The long-term objective of this project is to characterize the cognitive and linguistic mechanisms that underlie the spelling (writing) process, and the ways in which this process may be disrupted as a consequence of brain damage. The specific aims of the project are to:

1) evaluate the hypothesis that specific forms of spelling dysfunction (dysgraphia) result from damage to distinct components of the spelling process; and, 2) characterize in detail the internal structure of the components assumed to comprise the spelling system, thereby providing a basis

for a deeper understanding of the various forms of spelling disorders found in brain-damaged patients.

Methodology—These aims will be accomplished through a two-phase program of research. In the first phase, a large number of patients with focal brain damage will be tested with a spelling test battery specially designed to distinguish among various types of spelling disorders. Patients' performance on the test battery will be used to: 1) evaluate models of the spelling process; and, 2) define subgroups of patients with selective deficits to various components of the spelling process. In the second phase, patients with selective deficit to particular processing components (e.g., the component that stores knowledge of the orthographic structure of words) will be tested with sets of experimental tasks designed to probe in considerable detail the structure of the various components involved in spelling. Information generated from the detailed analyses in this phase of the project will be used to: 1) revise the test battery to better discriminate among

different types of spelling disorders; and, 2) evaluate specific hypotheses about the internal structure of particular components of processing.

Another major component of the proposed research involves the use of computational modeling techniques. This aspect of the proposed research will allow the formulation of a computationally explicit model of the spelling process, and the stimulation of spelling disorders by the "experimental lesioning" of the implemented model. Finally, the detailed characterization of spelling disorders in terms of damage to specific components of the cognitive/linguistic mechanisms that underlie spelling will be used to explore correlations between locus of brain damage and type of functional disorder.

Implications—The results of the proposed studies will contribute to a deeper understanding of the basis for spelling disorders in brain-damaged patients—an indispensable foundation for the diagnosis and remediation of dysgraphia.

[189] Stroke Clinical Center

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The major thrust of this project (primarily demographic in nature), is to assess the community profile of strokes for the state of Oregon. Our investigations emphasize therapies focused upon stroke patients in three broad areas of importance: 1) preventive therapy; 2) acute medical treatments; and, 3) rehabilitation intervention for higher cortical impairment.

Methodology—Preventive therapies are designed to assess various risk and prognostic factors in stroke patients to develop better molecular handles on both acute therapy and prevention. Factors which may yield to

better identification and therapy of risks are: mononuclear cell cholesterol ester hydrolase activity; glycosylated hemoglobin; cholesterol turnover in arteromatous plaques; and physicochemical bases for platelet behavior in stroke. Acute medical treatments focus initially upon the potentially beneficial assessment of prostacyclin infusion. In addition, staged, sequential evaluation of aminophylline/barbiturate and vasopressors will be continued in a prospective, randomized fashion. Rehabilitative intervention for higher cortical impairment deals with neuropsychological and language impairments with compensatory learning strategies.

[190] Hemispheric Specialization in Stroke Patients (Human)

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose/Methodology—Five experiments are proposed to investigate the hemispheric nature of long-term semantic

memory (LTSM). The experiments are designed for three subject populations: 1) stroke patients with unilateral

focal lesions; 2) (complete) commissurotomy patients; and, 3) normal subjects. The stimuli are pictorial and the responses are also nonverbal. The experiments measure the semantics of complex pictorial scenes, pictures of individual natural objects, artificial pictorial concepts, and logically defined concepts, as follows: 1) test memory for scenes, when the scenes have normal organization with respect to everyday life, such as familiar schemata (organized), lack organization, such as randomly juxtaposed objects (unorganized), or violate coherence by portraying parts of two conflicting schemata in the same picture (incongruous); 2) determine "mental distances" among concepts of natural superordinate categories with typicality levels of common objects serving as the guideposts; 3) study formation of "prototypical" concepts with the use of artificial (random-dot patterns) categories; 4) investigate the validity of the hypothesis

that the left hemisphere uses a logic-bound classificatory system, and that the right uses an experience-bound system for all concepts alike by the use of logically defined categories (e.g., odd number). Characterizing the mechanisms of functional asymmetries in the human brain is important for both basic scientific research and medical practice. Unilateral stroke, tumor, or missile wounds can cause devastating language, cognitive and memory disorders, and treatment for such impairments can improve only with increased understanding of hemispheric specialization.

Implications—The experiments proposed here should help gain direct insight into hemispheric mechanisms of a fundamental central processing module, namely, the conceptual system, LTSM, which plays a central role in modern cognitive scientific research.

[191] Treatment of Affective Deficits in Stroke Rehabilitation

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—Poststroke affective disturbances are pervasive (i.e., they affect anywhere from 40 to 65% of stroke patients). The diagnosis and treatment of these disturbances in stroke patients is a major untreated problem facing the medical rehabilitation community. Traditional approaches to diagnosis which have relied exclusively on verbal self-report or nonverbal expressions of depression have not adequately addressed either the communication difficulties of aphasics or some of the other cognitive disturbances (i.e., aprosody, minimization, concrete thinking), which limit the cognitive capacities of stroke patients. Furthermore, the effectiveness of various approaches to treatment has not been systematically studied in this population.

The aims of this study are twofold. The first aim is to validate a comprehensive diagnostic battery which permits an accurate examination of the affective disorders following stroke; the second is to evaluate the effectiveness of two approaches to treatment: antidepressants and cognitive therapy, when administered singly or in combination.

Implications—It is expected that greater accuracy in diagnosis and more aggressive treatment will significantly improve the quality of life of this subgroup of older Americans.

[192] Neural Basis of Motor Behavior

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—This proposal investigates the nature of the neural basis of motor behavior as a special window into higher brain functions. In this investigation, we link

sophisticated three-dimensional (3-D) computergraphic analyses of movement with experiments that allow us to infer underlying motor control processes performed

under conditions of failure of specific motor systems. All of the experiments that follow proceed from this unique vantage point and should mark a significant advance in our understanding of brain function for motor behavior.

Methodology—Five experiments are proposed that investigate performance of patients with damage to three central motor systems of the brain. *Neural Basis of Motor Planning and Control Experiments 1-3* study the neural basis of motor planning and control, beginning with the possible breakdown of a motor law, moving to the spatial control of hand trajectories, and finally to underlying brain processes for complex movements. *Neural Basis of*

Motor Equivalence Experiment 4 investigates the neural basis of a process of motor control integral to the production of speech as well as control of the limbs, that of motor equivalence. *Interplay Between Linguistic and Motor Behavior Experiment 5* begins the investigation of the interplay between neural control processes for linguistic and for motor behavior, from the study of a motor disorder in deaf signers.

Implications—These 3-D computergraphic analyses of movement should not only advance our understanding of the neural basis of motor behavior, but should also serve as a useful tool in evaluating diseases which affect the motor systems of the brain.

[193] Reduced CNS Injury and Improved Recovery with Gangliosides

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose/Preliminary Results—This proposal focuses studies on the acute effects of GM₁ ganglioside on central nervous system (CNS) injury processes in stroke. We have already found that ganglioside injections can decrease functional deficits and reduce mortality within 24 to 48 hours in rats that sustained substantial brain ablations. Subsequently, we found that ganglioside treatment limited cerebral edema, and reduced associated losses of CNS membrane, Na,K-ATPase activity, and intracellular K⁺ following cerebral trauma, as well as after denervation of subcortical regions. We have hypothesized that gangliosides reduce the extent of local CNS damage at the time of injury by preventing membrane failure, subsequent cell loss, and fiber degeneration. By limiting the extent of CNS tissue damage at the time of injury, conditions may be optimized for CNS regeneration and functional recovery. Most recently, we have begun studying the effects of ganglioside treatment on ischemia. Completed studies show that, after 48 hours, ganglioside treatment of gerbils with global ischemia results in a 48% decrease in mortality and protection from associated losses of membrane Na,K-ATPase activity. Using the rat model of focal cerebral ischemia (MCAo), this study examines in greater detail the

phenomena and molecular mechanisms by which gangliosides reduce pathological membrane events associated with CNS injury, and whether such acute effects result in reduced functional losses. In order to determine whether ganglioside treatment reduces functional losses immediately (1-72 hours) after the induction of ischemia, rats will be assessed on behavioral tests sensitive to cortical parietal damage (locus of primary infarct). Using light microscopy and tissue analyses, *in vivo* localization of (H3)GM₁ ganglioside will provide morphological evidence indicating where the CNS locus of action for these injected glycolipids might be. *In vivo* analyses of membrane components (ATPases and membrane fatty acids), and ions, which undergo changes during ischemia, will be assayed to focus on processes in the pathophysiology of membrane events associated with stroke and how these are affected by GM₁ treatment.

Implications—Studying these membrane events as a function of time will indicate whether the treatment prevents further spread of the ischemic damage. Aside from the therapeutic clinical implications, this study will provide insight into ischemic injury processes and the mechanisms by which ganglioside treatment is effective.

[194] Information Extraction from Peripheral Nerves

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—This work is directed toward providing better rehabilitation for people suffering from somatosensory loss and paralysis due to spinal cord injury, head trauma, or stroke. The goal of this project is to demonstrate that information suitable for controlling prosthetic devices, modulating functional electrical stimulation of muscle, and providing a sense of touch and position from areas of the body suffering sensory loss can be extracted, on-line and in real time, from recordings of sensory activity in peripheral nerves.

Methodology—This will be done by developing software that digitizes action potentials from multiunit recordings of peripheral nerve activity made with implanted intrafascicular electrodes; creating templates of the measured characteristics for identified single units; generating a decision tree that allows rapid

assignment of an action potential to one of the templates or to a "not identified" category; and measuring the distribution of activity among the set of identified units from recordings made during natural stimulation. Once this is completed, a prototype hardware system that can perform this analysis on-line in real time will be built.

Implications—While the thrust of this work is directed toward developing a microprocessor-based instrument capable of providing sensory feedback for controlling movement of hands and limbs in paralyzed patients, or for controlling stimulation of intact sensory systems to provide proprioceptive and tactile sensations from insensate regions, such a system would also be useful in research on the encoding and processing of sensory information by the nervous system.

[195] Brain-Injury Memory Disorders Research Center

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—This program proposal seeks support for a Memory Disorders Research Center dedicated to the study of the information-processing deficits underlying memory disturbances of individuals suffering brain injury or disease. These investigations will utilize contemporary research techniques and instrumentation to explore the on-line processing impairments of amnesic patients. This will permit greater understanding of the memory process, and will provide a basis for differential assessment and therapy.

Methodology—Four independent, yet interrelated projects are proposed. The first (Issues) focuses on unresolved issues of amnesia including an analysis of the relative contributions of episodic and semantic memory to implicit priming; compilation and organizational aspects of procedural learning; reconstruction and familiarity as aspects of contextual learning; and finally, factors underlying remote memory disturbances. The

second component (Case Studies) seeks to describe unique individual cases of amnesia both from a clinical and issue-driven experimental point of view. Alcoholic Korsakoff, postencephalitic, anoxic, bilateral temporal, retrosplenial, and selective stroke patients will be assessed for their dissociative memory abilities and disabilities. The third component (Neuroanatomy) explores the neuroanatomy of amnesia using neuroimaging techniques such as MRI and CAT scans. This will culminate in a greater understanding of the neural systems underlying memory and information processing. The fourth component (Assessment and Therapy) will develop an assessment battery to permit the differential diagnosis of amnesic patients along many of the dimensions explored in the Issues Component of this proposal. This assessment will then provide a basis for therapeutic attempts with some of these amnesic individuals.

The entire Center will be administered, organized, and monitored through the development of a Core

administration depicted in the fifth, and final component of this program project; including administrative assistance, secretarial support, consults, and educational opportunities. The entire program will thus

bring together research from otherwise diverse, and often disparate areas of investigation to explore the behavioral, cognitive, and neural underpinnings of amnesia.

[196] Ultra-Early Evaluation of Intracerebral Hemorrhage

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Spontaneous intracerebral hemorrhage (ICH) is a major public health problem, involving approximately 31,500 Americans yearly and resulting in more than 15,000 deaths. Approximately 1 of 10 strokes is an ICH. Benefit has not been established for any specific medical or surgical therapy. In an ongoing study of hyperacute therapy for cerebral infarction using tissue plasminogen activator, 20% of the patients arriving for care within 60 minutes of symptom onset have been excluded because of ICH. Active intracerebral bleeding was documented for two of these patients; for one patient, the active bleeding preceded clinical deterioration. These two cases, plus three other cases of documented active bleeding, prompted the investigators to review prior studies regarding the temporal profile of continued bleeding in the setting of spontaneous intracerebral hemorrhage.

Unfortunately, this question has not been appropriately addressed. If active bleeding continues for 1 to 6 hours following onset of spontaneous intracerebral hemorrhage, there may exist a "therapeutic window" during which therapeutic maneuvers such as blood pressure adjustment, administration of antifibrino-

lytic therapy, or ultra-early surgical evaluation may hold promise.

The primary study objectives are to determine: 1) the percentage of patients with ICH who have computerized tomography (CT) evidence of continued bleeding during the first hours after onset; and, 2) whether CT evidence of continued bleeding correlates with early clinical deterioration.

Methodology—We propose performing hyperacute evaluation of all stroke patients with CT within 3 hours of symptom onset. They will be examined at that time with a standard neurological examination. The CT scan will be repeated twice: once immediately after the first is completed, and again at 24 hours after initial symptom onset. The neurological examination will also be repeated at those times. Data will be gathered on each blood pressure measurement. Fifty-two patients will be studied over a 30-month period. Patients who expire will be examined at postmortem to determine the primary diagnosis and to determine, if possible, the reason for hemorrhage growth (if active in-hospital bleeding has been documented prior to death).

[197] Individualized Memory Prosthetic Device

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Approximately 500,000 persons suffer a traumatic brain injury (TBI) each year, with total annual costs estimated to reach \$4 billion. A large portion of TBI patients are left with permanent memory or other neurobehavioral deficits. The "Individualized Memory Prosthetic Device" (IMPD) will provide both rehabilitative treatment and long-term

cognitive support functions for patients who have experienced a TBI.

Methodology/Implications—The IMPD is based on a hand-held computer which prompts the patient in real time for the initiation and completion of tasks. The IMPD software is flexibly "data-driven" by a downloaded

therapist's prescription, and contains clock, calendar, alarm, and two-way communication functions to support cueing, monitoring, and reinforcement of patient behaviors. Therapist desktop software has been designed for the assessment and programming of the patient's IMPD-assisted therapy.

The perfected IMPD system will have immediate and direct applicability to other large clinical populations

suffering cognitive deficits induced by stroke, Alzheimer's disease, and other dementias. Additionally, the IMPD could be employed in normal populations for time management, habit training, other forms of behavior therapy, and as a "people meter," for use in both medical and marketing research.

[198] Reversible Focal Cerebral Ischemia

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—Reperfusion of ischemic tissues is presently thought to be potentially useful in the treatment of focal stroke. Pharmacologically- or surgically-induced reflow, however, might trigger another series of events more deleterious than those for persisting ischemia. The overall objective of this proposal is to determine the benefits of reperfusion as a function of ischemic duration and proximity of the tissue to the ischemic focus.

Methodology—The rat model of temporary middle cerebral artery (MCA) occlusion emulates the clinical manifestations of focal stroke, and is amenable to studies which will evaluate the viability of the focal and perifocal regions during reperfusion, after increasing periods of ischemia. Such studies will delineate the time threshold for irreversible damage not only in the ischemic core, but also in the perifocal region.

The focus of these studies is to evaluate the metabolic viability of the affected regions after varying periods of ischemia. Experience has shown that the different regions of the brain affected by MCA occlusion are relatively small. Microquantitative histochemistry resolves this problem by increasing our sampling precision of the

perifocal, focal, and normal tissue regions. Such a strategy, however, requires supporting techniques to identify the regions of interest, and to that end, autoradiograms from quantitative cerebral blood flow measurements are a guide to dissection of lyophilized tissue. Administration of C-2-deoxyglucose during ischemia delineates the site of the original ischemic focus. Routine histological studies are planned and electrophysiology performed when required to complement the metabolic data.

Preliminary Results/Implications—Preliminary studies with proton magnetic resonance imaging indicate that this noninvasive procedure provides a natural history of edema formation and resolution, and the metabolic correlates to these changes will be determined. The clinical management of an acute ischemic insult to the brain remains problematic. Until the events leading up to death or infarction are established in focal ischemia, little insight can be gained on how to improve therapy.

The proposed study will provide new information on the recovery process in the focal and perifocal regions, if they differ, and whether unique forms of intervention should be tried to improve the safety of reperfusion.

[199] Quantitative Histopathology of Multifocal Cerebral Ischemia

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—Stroke is the third leading cause of death in the United States, and the primary cause of neurologic morbidity. Vascular causes of dementia are the second

most common cause of dementia in elderly Americans. No specific therapy currently exists for either stroke or cerebral vascular dementia. The failure to develop

effective therapy for these diseases may be partially the result of the absence of a reproducible animal model of this type of cerebral vascular disease.

Methodology/Implications—We have developed new animal models that allow for the rapid and inexpensive testing of new drugs that may be effective in the treatment of cerebral vascular disease. We propose to extend our previous observations by refining a method for the quantitative analysis of the histopathologic consequences of

multifocal cerebral ischemia on behavior (learning). We hypothesize that learning behavior will change in a measurable way depending on the topographic distributions of lesions following ischemia, and that these observations will be altered by pharmacologic therapy.

These methods will allow us to screen new drugs for their potential benefit in the treatment of victims of stroke or vascular dementia, and will provide insights into the mechanisms underlying the dementia apparent in many patients with vascular lesions.

[200] Neurotransmitter Release: Role in Ischemic Injury

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Purpose—The major goal of this project is to explore the role of dopamine (DA) in the development of ischemic neuronal damage in the dorsolateral striatum. We hypothesize that ischemia-induced release of specific neurotransmitters and/or neuromodulators (i.e., DA) to the extracellular fluid is essential for the development of ischemic neuronal damage in vulnerable brain regions (i.e., striatum). The protective effect of substantia nigra (SN) lesion might be associated with the inhibition of DA release during ischemia.

Methodology/Implications—Using the microdialysis technique, we will document the effects of specific striatal deafferentation, and a nonspecific lesion near the SN on extracellular levels of DA in the medioventral and dorsolateral striatum, during and after transient global ischemia. We will then determine whether attenuation of ischemia-induced neuronal injury in the dorsolateral striatum is specific to dopaminergic deafferentation, or can be reproduced by other lesions. Since the susceptibility of the striatum may be associated with post-ischemic uncoupling of blood flow and metabolism, we will evaluate, by autoradiographic strategies, changes in local cerebral blood flow and glucose metabolism induced by transient global ischemia, and determine

whether they can be affected by specific and nonspecific pathway lesions.

Further studies will be performed to characterize the specificity of the protective effect of the SN lesions by evaluating its time-course, and its effects on glial cell activity in the striatum. In attempting to develop a novel pharmacological paradigm for treatment of stroke, we will evaluate whether post-ischemic neuronal injury can be attenuated by pharmacological modulation directed toward: 1) the depletion of DA; or, 2) inhibiting specific DA receptor.

We hypothesize that such a pharmacological modifier might attenuate ischemic damage, and could lead to an appropriate therapeutic strategy in the treatment of brain ischemia. A related issue stems from our recent finding demonstrating that acute and massive release of extracellular norepinephrine (NE) occurs in the hippocampus during ischemia. We will explore the role of NE in the development of delayed neuronal damage in the hippocampus by evaluating the effects of locus coeruleus lesions and pharmacological modulation of NE activity on the development of morphological and biochemical measures of ischemia in the hippocampus. We hypothesize that increasing NE activity may prove to be beneficial in delaying or ameliorating hippocampal neuronal damage.

[201] 1989 Gordon Research Conference on Neural Plasticity

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The Gordon Research Conference on Neural Plasticity has been held every alternate year since 1977 at Brewster Academy, Wolfeboro, NH. Gordon Research Conferences (GRC) were established to stimulate ideas in an informal setting. Uninhibited discussion is fostered by GRC strictures on the publications, proceedings, or indeed the citation of presentations.

The format has proved particularly useful in the Conference on Neural Plasticity—a highly interdisciplinary meeting in which the subject of modifiability of the nervous system is examined at the molecular, cellular, and systems levels, and in which the participants come from broadly different backgrounds (biochemical, pharmacological, anatomical, electrophysiological, and behavioral). One evening is set aside for a keynote speaker

and poster session. The remaining eight sessions will focus on specific issues, with three or four scheduled speakers, so that significant time is preserved for discussion. The discussion tends to continue informally during the afternoon, when no formal sessions are scheduled.

It is the experience of participants that these informal interactions are often more fruitful than the extended sessions characteristic of other meetings. The formal program includes sessions on: cellular and molecular models of learning, learning in the adult cerebral cortex, genetic and hormonal models of neural development and plasticity, regulation of neuronal receptors, oncogenes and neural plasticity, neural grafting, NMDA receptors and long-term potentiation, and the role of ion channels in neural plasticity.

[202] PET Study of Biochemistry and Metabolism of the CNS

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Purpose—A Positron Emission Tomography (PET) Facility has been established at the University of Michigan for the development of a new, noninvasive approach to human brain research utilizing positron-emitting metabolic and pharmacologic probes. A dedicated TCC CS-30 medical cyclotron, a TCC PCT-4600A tomographic scanner, the radiochemical/radiopharmaceutical facilities, and a small image-processing computer facility will be used in the performance of PET studies and complement the existing Nuclear Medicine facilities.

Methodology—Proposed studies involve the use of positron-emitting probes 15-O-C0, 15-O-H2O, 15-O-02, 18-F-2-deoxyglucose, 11-C-BCNU, 68-Ga-EDTA, and 11-C-scopolamine to study cerebral blood volume, blood flow and partition coefficients, oxygen utilization,

glucose utilization, tumor uptake, blood-brain barrier integrity, and muscarinic receptors respectively. Patients with Huntington's disease, epilepsy, brain tumors, the hypotonic and hypertonic phases of paralysis associated with stroke, dystonia, olivopontocerebellar atrophy, and aging in the human brain will also be studied. Studies of the normal brain with several agents will continue. New positron-emitting radiopharmaceuticals will be synthesized, and new labeling techniques will be investigated. 11-C-scopolamine will be available for high specific activity *in vivo* receptor studies, and 11-C-amine cyclopentane carbocyclic acid (ACPC) will be developed for amino acid uptake studies. New physiological modeling techniques will be instituted for mapping receptor sites. Parameter estimation techniques will be developed to determine rate constants from dynamic PET studies of FDG metabolism.

[203] Cerebral Ischemia, Viability and Oxidative Metabolism

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Purpose—Our overall goal is to utilize intracellular indicators of oxidative metabolic activity to assess the changes that occur during cerebral anoxia/ischemia, and to determine the factors most critical to overall tissue viability during and following periods of circulatory compromise.

Methodology/Implications—Noninvasive techniques of fluorometrically monitoring changes in the reduction/oxidation ratio of intramitochondrial NAD, and the technique of reflection spectrophotometry to measure redox changes of cytochromes, together with changes in

hemoglobin oxygenation and local blood volume will be utilized. By relating parameters of metabolism and function, we will discern how the vulnerability of functional activity is associated with periods of ischemic insult.

We will continue efforts to define the relationships between energy metabolism and the functioning of the central nervous system to increase our understanding of how and why the brain uses oxygen, metabolic substrates and oxidative energy, and to determine how viability is threatened by the loss of oxygen and circulatory perfusion.

[204] Head Injury Clinical and Laboratory Research Center

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The main objective of this Head Injury Clinical and Laboratory Research Center is to establish a system whereby rational and improved therapies for patients with head injury can be defined, developed, and tested scientifically. To accomplish this objective, the proposed program will: 1) define the physiological, morphological, metabolic, and psychosocial sequelae of head injury in man; 2) collect, assemble, and analyze data from head-injured patients to formulate an accurate prognosis; and, 3) define in a well-controlled animal model the anatomical, physiological, and biochemical effects of injury on brain parenchyma and blood vessels, and on systemic function.

Methodology—The influence of systemic insults to the injured brain will be studied both in man and in animal models. Evaluations will be made in humans of therapy for brain acidosis, elevated intracranial pressure, ischemic and hyperemic cerebral blood flows, neurophysiological status, and posttraumatic mental depression. The role of iatrogenic hypocapnic alkalosis in the management of patients will be clarified. The unifying hypothesis to be

tested is that the brain parenchyma and its intrinsic vasculature can sustain reversible injury. These tissue elements can be rendered dysfunctional; yet, such dysfunction does not implicate irreversible disruption. The dysfunctional state may be temporary, and if the internal milieu is appropriate for healing, the cells can recover. Dysfunction may be represented by reduced, excessive, or aberrant metabolism.

An animal intensive care unit and a controlled brain injury model provide the experimental environment. Acute and chronic animal studies will be conducted on morphologic neural and vascular changes, brain glucose utilization, cerebral microcirculation, the brain arachidonic acid cascade, regional cerebral blood flow, and surface brain energy metabolism following controlled brain injury. Therapy will be tested by studying cerebral acidosis and treatment with THAM.

Implications—We seek to understand the fundamental basis of neuronal loss after injury, and by intervention, to reverse the process.

[205] Center for Stroke Research

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—Our objective is a better understanding of the pathophysiology of stroke. The program features an integration of the research activities of the Departments of Neurology, Neurosurgery, Neuropsychology, and Diagnostic Radiology in the study of cerebral vascular disease. The research emphasizes and explores the utility of 31-P Topical Nuclear Magnetic Resonance (TMR) proton spectroscopy, and proton NMR imaging in the study of brain anatomy, cerebral blood flow (CBF), and energy phosphate metabolism in clinical patients with stroke.

Methodology—Administrative, statistical, and methodological cores and four individual projects are proposed. The methodological cores describe the NMR facility, CBF laboratory, and neuropsychological laboratories.

Project 1 proposes early experiments toward the development of NMR methods for the eventual autoradiographic measurement of CBF. The second project

explores the dynamic changes in cerebral energy metabolism as measured by 31-P NMR and 1-H in cat models of global and focal cerebral ischemia.

Studies of the clinical patient with stroke begin in Project 3 with a proposal to improve and explore the utility of the ¹³³xenon inhalation technique for the measurement of CBF, and to establish abnormal CBF as a risk factor for stroke.

Project 4 proposes to apply 31-P and 1-H spectroscopy, together with NMR imaging, to the study of the clinical patient with diffuse hemispheric ischemia and focal ischemic infarction.

Future Plans/Implications—The eventual goals of this Program Project are to establish noninvasive techniques to identify hemodynamic and metabolic markers which permit the logical and safe therapy of acute and chronic ischemia in cerebrovascular disease by either medical or surgical means.

[206] Reorganization in Brain and Spinal Cord After Injury

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—The goal of this project is to continue our studies of the mechanisms underlying the responses of the central nervous system (CNS) to injury, and the basis for the partial recovery that can occur with time.

Methodology—Animal models of CNS lesions affecting adult humans will be created in mature animals with ablations of the cerebral cortex, and with kainic acid and 6-hydroxydopamine-induced lesions of the basal ganglia and thalamus. Animal models of CNS injury affecting immature humans will be produced in neonatal animals with ablations of the cerebral cortex and with cerebral

lesions induced by hypoxic-ischemic insults. A central focus concerns the immediate and long-term responses to injury of CNS neurotransmitter receptor systems, including glutamate, Gamma-aminobutyric acid/benzodiazepine, opiates, dopamine, and acetylcholine.

Investigations will be performed using awake-behaving animals, tissue from basal ganglia, thalamus, brainstem and spinal cord, and neuronal cell cultures. The experimental approaches include recordings of single neuronal unit activity, studies of neurotransmitter receptors, determinations of glucose metabolic activity, and investigation of ionic conductances in mammalian nerve cell membranes.

[207] Precursors of Stroke Incidence and Prognosis (Human)

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Purpose—It is proposed to extend the prospective findings of the Framingham Study on stroke to 30 years of follow-up, including the age groups 75 to 84 years, and to examine a number of possible precursors for which there has been too little follow-up. These include the roles of: arrhythmias as determined by one-hour ECG monitoring; echocardiographic findings of valvular and myocardial dysfunction; lipid profiles including LDL and HDL cholesterol; physical activity status; menopausal status; psychosocial factors including Type A personality; carotid bruit; Ecolyzer-confirmed smoking histories; and, glucose tolerance based on a glucose load, among others.

Future Plans/Implications—Further studies of asymptomatic carotid bruits will be carried out by analyzing the continuous wave Doppler signal for its direction, mean frequency, and frequency content, as they are found at selected moments in the cardiac cycle, over the carotid arteries in the neck, and phonoangiography of carotid bruit in an attempt to identify those bruits which are true precursors of stroke. A more accurate delineation of the type of stroke will be accomplished using CT scan infor-

mation in addition to clinical findings. This should permit better definition of the frequency of different types of stroke and a more accurate determination of the epidemiologic features of each type.

The stroke, its precursors and disability, will be pursued, focusing particularly in the elderly. Functional assessment of the patient's activities of daily living will be made at the time of stroke, and 3, 6, and 12 months later. Scores on recently standardized tests, scales of activities of daily living (e.g., feeding, dressing, grooming, bathing, etc.); assessments of function in the home and in society; and, the use of aids and appliances following stroke will be obtained by a rehabilitation nurse. These data will permit detailed evaluation of disability following stroke in a general population sample.

An attempt will be made to devise a more powerful predictive stroke-risk profile using those ingredients identified above as independent contributors to stroke incidence. The decline in mortality rates from stroke has accelerated in recent years. Secular trends in incidence by stroke type will require more cases occurring over time and should be available as a by-product of this proposal.

[208] Manipulation of Adenosine Metabolism and Control of Stroke

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Purpose/Methodology—Stroke and cardiac arrest constitute two of the most frequent causes of death in the United States and even when patients survive it is frequently with some degree of neurological impairment. A massive release of the excitotoxic amino acids, glutamate and aspartate, occurs in the brain during ischemia, and these, together with calcium entry into depolarized nerve cells and the generation of toxic oxygen-derived free radicals, are considered to be major causes of ischemic cellular damage. Adenosine, which is also released in the ischemic brain, attenuates the release of these excitatory amino acids and acts as an antagonist at membrane

calcium channels. The adenosine metabolites hypoxanthine and xanthine are substrates for an enzyme, xanthine oxidase, which generates free radicals.

The first objective of this proposal is to use two potent inhibitors of adenosine deaminase, the enzyme which metabolizes adenosine to the inert product inosine, to elevate adenosine levels in the ischemic brain and to thus reduce excitatory amino acid release and membrane calcium permeability with the ensuing neuronal damage. Inhibition of adenosine deaminase also results in a decrease in hypoxanthine formation, thus depriving xanthine oxidase of its substrate, reducing free radical formation.

Secondly, inhibitors of xanthine oxidase will be used to reduce free radical formation. Neurochemical experiments on amino acid and purine release from the rat cerebral cortex will be coupled with studies on the degree of actual protection against stroke deficits conferred by treatment with adenosine deaminase or xanthine oxidase inhibitors.

Implications—The findings from these experiments could lead to the development of prophylactic and thera-

peutic uses of these enzyme inhibitors in individuals at risk for cardiac arrest or stroke. An obvious alternative approach for the use of purines in the treatment of cerebral ischemia would be direct administration of a stable adenosine analog. The disadvantage of this strategy, apart from the fact that these compounds may not cross the blood brain barrier, is that they also have potent hypotensive effects. Manipulation of the metabolism of endogenously released adenosine avoids these potential complications.

[209] Microvascular Occlusions: Acute Focal Cerebral Ischemia

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Purpose—The overall objectives of this proposal are to examine the contribution of acute microvascular occlusions in the lenticulostriate territory to the extent of cerebral ischemia following acute middle cerebral artery stroke in a nonhuman primate model and to assess the mechanism by which those occlusions are generated. The hypotheses to be tested state: 1) that LSA microvascular occlusions are secondary to the adherence of (and vascular obstruction by) PMN leukocytes and/or tissue factor-mediated stasis thrombosis; and, 2) that established monoclonal antibodies against leukocyte adherence and TF activity will decrease occlusion numbers and infarction volume, and improve neurological outcome. The finding of occlusions containing blood elements in the microcirculation of the LSA territory following MCA occlusion and subsequent reperfusion in the primate acute stroke model suggests a pathogenesis for the "no-flow" phenomenon in focal cerebral ischemia. Measures which reduce the extent of this phenomenon in cerebral ischemia may reduce the region of focal cerebral ischemia and improve neurological recovery. Heretofore, this concept has not been testable.

Methodology—The mechanism of microvascular occlusion formation as defined by the ability of MoAb to inhibit occlusion formation, and the neurological consequences of these interventions will be developed in stages: 1) the presence of PMN leukocytes in the LSA microvasculature will be identified and quantitated by India ink/glutaraldehyde/light microscopy, and the vascular PMN leukocyte and platelet morphology will be defined by electron microscopy in short-term (5-hour) experiments; 2) the development of LSA microvascular occlusions will be monitored by vascular occlusion score and by in-platelet deposition in the ischemic corpora striata of intact formalin-fixed brain by g-camera imaging in short-term (5-hour) experiments; and, 3) the ability of microvascular occlusion inhibition by MoAb to decrease infarction volume and improve functional outcome will be assessed in long-term (14-day) experiments in the primate model.

Implications—This approach may have significant consequences for acute stroke patient management.

[210] Biochemical Mechanisms of Brain Injury

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Previous experiments indicate that following experimental concussive brain injury, the oxygen-free

radicals produced during cyclooxygenase metabolism of arachidonic acid cause endothelial lesions, dilation,

reduced responsiveness to hypocapnia and abnormal responsiveness to acetylcholine and bradykinin, and may be responsible in part for stimulating arachidonic acid metabolism following injury. We therefore wish to test the following hypotheses. *Hypothesis 1:* Following concussive brain injury, receptor-mediated mechanisms contribute to an increased metabolism of polyunsaturated fatty acids and the production of oxygen radicals which cause cerebrovascular and brain dysfunction. *Hypothesis 2:* Pharmacologic inhibition of fatty acid metabolism, free radical production, or free radical action will reduce the cerebrovascular dysfunction caused by traumatic brain injury.

Our general aims are to understand: 1) factors responsible for initiation and regulation of fatty acid metabolism following injury; 2) the pathways and products of this metabolism; 3) the cerebrovascular consequences of increased fatty acid metabolism and radical

production; and, 4) how pharmacologic intervention can prevent, reduce, or reverse the injury process.

Methodology—To accomplish our aims, we will utilize microscopy and radioimmunoassay to correlate simultaneous *in vivo* arteriolar diameter responses, and *in vivo* cyclooxygenase and lipoxygenase synthetic responses. We will employ gas chromatography/mass spectrometry to identify and measure fatty acids and their metabolites.

Implications—Little is known about regulation of the changes in fatty acid metabolism, and the concomitant cerebrovascular consequences of increased oxygen radical production following brain injury. The proposed studies will address these problems and are consistent with our long-term goal of elucidating chemical mediators of, and therapeutic agents for, brain injury.

[211] Treatment of Physiological Disturbances in Head Injury

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Purpose—Central nervous system injury is a dynamic process. The initial insult, resulting in primary neurological injury, sets into motion secondary pathological processes which compound the initial injury and adversely affect the outcome. These secondary processes include ischemia, hyperemia, edema, hypermetabolism, acidosis, inflammation, and delayed hematoma formation. To optimize neurological recovery, specific methods of monitoring for and treating each of these phenomena are needed. This program project represents an interdisciplinary research effort by the Departments of Neurosurgery, Neurology, Pediatrics, and Pathology of the Baylor College of Medicine. The aim of the project is two-fold: 1) to clinically test new therapies, and systems for continuous monitoring, that have recently been developed;

and, 2) in a laboratory setting, to devise new therapeutic strategies for the common secondary insults associated with head injury-ischemia, inflammation, and delayed hemorrhages.

Methodology—The project consists of six closely related scientific proposals and three supporting Core units: 1) treatment of the hypermetabolic response to CNS injury; 2) monitoring adequacy of cerebral perfusion in head-injured patients; 3) continuous monitoring of intracranial compliance by ICP waveform analysis; 4) characterization and treatment of the inflammatory response to CNS injury; 5) reduction in CNS injury by modification of ischemic energy metabolism; and, 6) prevention of hyperemia and hemorrhage in the newborn brain.

[212] Epidemiologic Study of Stroke Outcome in Three Ethnic Groups

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Despite the reported decline in the incidence of stroke, there has not been a decline in stroke recurrence. Relatively little is known about whether ethnicity, independently or in conjunction with stroke risk factors, determines outcome after cerebral infarction. Most epidemiologic studies have been conducted in predominantly white populations. Less is known about black survivors of cerebral infarction, and few studies have been done in the growing Hispanic population. The study is designed to determine in whites, blacks, and Hispanics the risk of stroke recurrence, myocardial infarction, and death in 30-day survivors of cerebral infarction up to 10 years after an index event.

Methodology—Members of the cohort were admitted to the Neurological Institute of New York from 1983 to 1988. The majority are from northern Manhattan, a community with many black and Hispanic residents. Columbia-Presbyterian Medical Center is the main provider of ambulatory and hospital care for this community. Risk factors for stroke, infarct subtype, and findings on neurological examination and diagnostic studies,

identified at the time of the initial cerebral infarction, have already been collected on the systematically evaluated cohort.

Annual telephone follow-up of the patient or next of kin will be used to measure changes in risk factors, and to identify those with stroke recurrence, symptomatic myocardial infarction, or death. In-person follow-up interview and examination will be done on patients suspected of a subsequent event. Outcome after cerebral infarction will be analyzed by life table methods and Cox proportional hazards modeling. Stratification, or the addition of other collected variables to the models, are expected to show that the effect of ethnicity is not independent of other risk factors.

Implications—Besides gaining new epidemiologic information on the risk and determinants of stroke recurrence, myocardial infarction, and death after cerebral infarction in three ethnic groups, understanding the role of individual risk factors and their interactions with ethnicity will encourage more selective secondary prevention strategies.

[213] Calcium Channel Activation in Models of Cerebral Ischemia

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose/Methodology—We used *in vivo* and *in vitro* autoradiography and ^3H -nimodipine, a dehydropyridine calcium channel antagonist, to study rat brain at various intervals after focal cerebral ischemia. The severity of ischemia was graded by blood flow measurements performed at the same time in separate rats.

Results/Implications—We observed that *in vitro* autoradiography was inadequate as a means to study binding in focal cerebral ischemia, since the act of decapitation activated the cortical binding sites diffusely, and the preceding focal ischemia became unapparent. Conversely, *in vivo*, a very dynamic picture of both

regional and duration-dependent binding to nimodipine was evident.

Comparison to CBF data indicated that the most ischemic regions show the earliest activation of nimodipine binding. As these regions lost their activation, more moderately ischemic regions exhibit activated binding.

Future Plans—We therefore propose to test the hypothesis that loss of nimodipine binding in a previously activated region is associated with infarction, while slower but more persistent activation characterizes salvageable tissue.

We then propose to compare control ischemia to the results obtained when calcium channel or NMDA

receptor antagonists are administered after the onset of ischemia. Using positron-emitting ^{11}C -nimodipine synthesized here, we propose to use PET to study the effect of

varying ischemic severity on nimodipine binding in baboon brain and, with the same techniques, investigate the natural history of nimodipine binding in stroke patients.

[214] Modulation of Glucose Transporters in Brain Endothelium

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Purpose—The prime requirement for glucose, both as a fuel and as a source of growth by brain and nervous tissue, makes it especially important to understand the molecular events that govern glucose homeostasis in these tissues under normal as well as diseased conditions. The first step in cerebral metabolism of glucose is its transport into the tissue. The interface between blood and brain is comprised of a layer of endothelial cells which is the site of glucose transport. The long-term goals of this research are to characterize the molecular events whereby D-glucose is transported transcellularly from the plasma to the interstitial fluid of the brain. These goals include an understanding of where the transporters are located, and how transport activity is regulated.

Methodology—To investigate the brain endothelial cell glucose transporter, a polypeptide and the amino acid sequence of the C-terminal end of the glucose transporter will be synthesized, and antiserum against this peptide will be prepared. This antibody will be used to localize the glucose transporter on brain sections, and on cultured endothelial cells by light immunocytochemistry, and to determine the distribution and abundance of the glucose transporter on the luminal, abluminal, and subcellular

membranes of brain endothelial cells by ultrastructural immunocytochemistry.

Cultured dog brain endothelial cells will be used as a model of the blood-brain barrier to determine the abundance of glucose transporters under conditions of anoxia, hypoglycemia, and hyperglycemia, or exposure to phorbol ester and insulin. The Mongolian gerbil occlusion model will be used to determine the response of the brain endothelial cell glucose transporter to ischemia, and for up to 72 hours post-ischemia. An oligonucleotide probe complementary to the known mRNA sequence of the glucose transporter will be synthesized and labeled. This probe will be used to examine regulation of the glucose transporter at the transcriptional level by *in situ* hybridization of glucose transporter mRNA in the ischemic gerbil model, and in Northern blots of TNA derived from the cultured brain endothelial cell model.

Implications—Understanding the mechanisms by which glucose is transported across the blood-brain interface, and the alterations of this glucose transport system induced by abnormal conditions or by therapeutic agents, will have important bearing on human brain metabolism and brain function during and subsequent to strokes, cardiac arrest, and metabolic encephalopathies of diverse types.

[215] Post-Ischemic Hyperexcitability: The Role of Adenosine

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Purpose—The factors which render certain cells sensitive to transient ischemia remain largely unknown. In the selectively vulnerable CAL region of the hippocampus, neuronal hyperexcitability has been implicated in the process of post-ischemic cell death. The reason for post-ischemic hyperexcitability in the CAL region is unknown,

but is likely to reside in a disturbance of one or more of the inhibitory or excitatory mechanisms which normally serve to control the output of these cells. This proposal will examine the specific hypothesis that a change in the efficacy of adenosine neuromodulation participates in the process of CAL cell loss by directly contributing

to post-ischemic hyperexcitability in this selectively vulnerable region.

Adenosine is among the strongest modulators of neuronal activity in the vulnerable CAL region of the hippocampus. This purine nucleoside is a potent inhibitor of neuronal discharge, and appears to function as an endogenous anticonvulsant in CAL. Specific membrane receptors mediate the inhibitory action of adenosine and the regional density (i.e., number) of these receptors is a critical factor in determining the strength of adenosine action. Following transient ischemia, these receptors are decreased in number in the vulnerable CAL region and this decrease is correlated temporally with the onset of post-ischemic hyperexcitability. These observations lead to the hypothesis that the post-ischemic reduction of adenosine receptors contributes to post-ischemic hyperexcitability by attenuating the strength of the endogenous, inhibitory action of adenosine. The studies proposed in

this application will: 1) elucidate the role of adenosine neuromodulation in post-ischemic hyperexcitability; 2) identify the cellular site of adenosine action impacted by transient ischemia; 3) establish a model system for the examination of vulnerable and nonvulnerable CAL pyramidal neurons; and, 4) examine the trigger mechanism for the post-ischemic loss of adenosine receptors.

Implications—The effects of transient ischemic episodes, such as occur in conjunction with cerebrovascular and cardiovascular disease, are often debilitating. Identification of the critical factors responsible for post-ischemic neuronal vulnerability will clearly aid in the development of appropriate strategies for treating or preventing these deficits. This proposal will play an important role in this process by providing direct information on the relation between post-ischemic cellular dysfunction, and the reduced efficacy of adenosine neuromodulation.

[216] Role of Magnesium in the Pathophysiology of Brain Injury

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose/Methodology—Head injuries pose a significant and unique health problem in the United States. Of people that survive head trauma, over 60,000 each year experience residual neurological dysfunction. These neurological deficits appear to be caused by direct mechanical disruption of neuronal pathways, and through secondary or delayed mechanisms that develop over a period of hours to days following the traumatic insult. Although part of the delayed damage to the central nervous system (CNS) after traumatic injury appears as a result from the release or activation of endogenous autodestructive factors, the fundamental mechanisms underlying secondary injury are poorly understood and current therapies are largely unsatisfactory.

Recent work from our laboratory suggests that decline of brain magnesium (Mg) may be a critical factor in the pathophysiological sequelae of traumatic brain injury. Because Mg is mandatory for all ATP-producing and ATP-consuming reactions, it regulates the cellular bioenergetic state and exerts considerable control over a large diversity of metabolic and ionic flux pathways. Changes in tissue Mg will therefore

be a common mechanism linking apparently unrelated CNS injury factors and the response to specific treatments.

The proposed studies will examine the pathophysiological role of Mg in secondary brain injury, using a model of fluid-percussion traumatic brain injury in the rat. Changes in total, extracellular, and intracellular free brain Mg concentrations after brain injury will be characterized and related to time course and injury severity. Magnesium changes will also be correlated with alterations in cellular bioenergetic state (^{31}P NMR), mitochondrial respiratory function, as well as changes in other brain cation concentrations (Ca, Na, K, Zn), and tissue water content. The effect of Mg deficiency (dietary restriction) and Mg supplementation on neurochemical, histopathological, and neurobehavioral outcome after brain injury will be examined. To evaluate the role of the magnesium-gated excitatory amino acid (EAA) ion channel in brain injury, non-competitive EAA receptor antagonists MK-801 and CGS-19755 will be evaluated, with and without Mg supplementation, for their efficacy in the treatment of brain injury.

Implications—These studies will expand our understanding of the fundamental pathophysiological mechanisms that contribute to irreversible tissue damage after trau-

matic brain injury, and may lead to the development of effective new therapeutic approaches for the treatment of brain injury.

[217] Biochemical Receptor Studies in Stroke (Rats, Rabbits)

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Catecholaminergic systems have been implicated in both the pathogenesis of stroke and the recovery of function after ischemic injury. This proposal is designed to further elucidate the structure, regulation, and function of the α_1 -adrenergic receptor (α_1 -AR) for catecholamines. In the control of the cerebral circulation in man, α_1 -AR mediated events may play a role. In addition, the α_1 -AR may directly influence cellular metabolism through the putative second messengers inositol triphosphate and diacylglycerol. This may be important for the understanding of neuronal growth, plasticity and altered neurotransmission. The work has three specific aims: 1) to develop technologies for the purification of the necessary quantities of receptor protein; 2) to raise antibodies directed against the α_1 -AR; and, 3) to develop

a system for the reconstitution of the α_1 -AR into phospholipid vesicles.

Methodology/Implications—Purification of the receptor protein will be accomplished through sequential affinity chromatography, wheat germ agglutinin chromatography, and high performance steric-exclusion liquid chromatography. Purified receptor will then be employed to immunize rabbits for the production of antibodies. A reconstitution system will provide a means of assaying the activating function of the receptor and a way of studying the mechanisms by which the receptor-effector system is regulated. Combined with previous work, the availability of these biochemical tools will permit further study of the α_1 -adrenergic receptor at the molecular level.

[218] Disorders of Spatial Behavior in Right Brain-Damaged Stroke Patients

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Sponsor: *Nijmegen Institute for Cognition Research and Information Technology*

Purpose—Adequate processing of spatial information is essential for the performance of sensorimotor tasks. Some specific defects concerning the processing of spatial information can be observed in stroke patients with a lesion in the right posterior cerebral cortex. These include a neglect for the contralateral space, under- and/or overshoots in reaching, and a visuomotor apraxia. Although these disorders are clinically well-documented, little is known about the way basic information processing systems are disturbed.

Methodology—A series of experiments were performed focusing on the understanding of neglect at a rather

fundamental level. In a first series of experiments, subjects had to react as quickly as possible to visual or auditory stimuli coming from right or left. In one condition, the subjects had to press a button, whereas in other conditions, they had to move toward (left or right) targets. The cognitive difficulty of the task was manipulated across conditions (compatible versus noncompatible task conditions).

Future Plans—In a second series of experiments, subjects will have to perform a sequence of reaching tasks toward static (nonmoving) and dynamic (moving) targets.

[219] Long-Term Effects of Closed Head Injury: A Disability- and Handicap-Oriented Study

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Sponsor: WVC; NIZW

Purpose—The aim of the present project is to describe the epidemiology of traumatic brain injury in the Netherlands and to deliver information about the actual life situation of brain-injured subjects.

Methodology—One hundred and twenty-one subjects (and their relatives) were interviewed and neuropsychological checklists were utilized. People were studied in

their home situation, 3 to 7 years after the accident. At the time of the accident all subjects were between 15 and 30 years of age.

Preliminary Results—The preliminary results revealed that 65% of the subjects suffered from more or less serious behavioral problems (e.g., attentional deficits, memory problems, fatigue, and headache).

[220] Development of a Multidisciplinary Measurement System for the Quantification of Deficits Following Traumatic Brain Injury

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Sponsor: Société de l'assurance automobile du Québec; Fonds de la Recherche en Santé du Québec

Purpose—The long-term objective of this project is to establish a multidisciplinary measurement system which will be used to quantify the deficits, impairments, and handicap following a traumatic brain injury (TBI). The computer-based system will provide the basis for an integrated multi-center data acquisition system which will track the progress of clients from their arrival at an acute care hospital via their rehabilitation up until the time of their return to the community.

Progress—The first three years of this 5-year project have been devoted to the selection and/or development of quantitative clinical tools which will form the basis of the measurement system. Appropriate clinical tools have been identified to measure deficits in the following domains: medical, neurophysical, psychological, activities of daily living, leisure, social, communication, and vocational. Present studies are investigating the validity and reliability of the various components. An integral part of the development of the measurement system has been the establishment of a longitudinal study which serves as a means for evaluating the clinical feasibility and sensitivity of the system components. The longitudinal study, which currently involves a neurosurgical unit and a

rehabilitation center, follows patients during the 2 years subsequent to their injury.

Results—To date, 68 severe (Glasgow Coma Score ≤ 8 or intracranial surgery) TBI patients who were involved in a vehicle-related accident have been followed as part of the longitudinal study. The data obtained from these patients have been entered into the system database.

Future Plans—Statistical analyses will be performed to reduce the number of variables and to isolate key descriptors of recuperation/rehabilitation. The final version of the measurement system will be computerized to permit optimum data management. The system, when completed will be introduced into a number of hospitals and rehabilitation centers in order to provide a comprehensive understanding of the evaluation and evolution of the TBI patients and the impact of specific rehabilitation strategies.

Recent Publications Resulting from This Research

Motor Recovery Following Severe Traumatic Brain Injury. Sullivan SJ et al., in Proceedings of the S.M. Dinsdale International Conference in Rehabilitation, 1990.

An ADL Profile of the Adult with Severe Head Injury. Dutil E et al., Occupational Therapy and Health Care (in press).

VII. Independent Living Aids

For additional information on topics related to this category see the following Progress Reports: [10], [171], [175], [429], [430], [456], [459], [466], [491], [506].

A. General

[221] Access and Mobility Requirements for Children and Adolescents

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Sponsor: *Channel 7 Children's Medical Research Foundation of S. Australia, Inc.*

Purpose—This research was undertaken because of difficulties experienced in designing school buildings to be accessed by children and adolescents with physical disabilities. No previous research had produced design data for access to buildings by young people with disabilities. The hypothesis of the study was that the physical access needs of disabled young people are not the same as those of disabled adults or able-bodied young people, and the extent of their requirements could be defined.

Methodology—The young people included in the study were 288 children and adolescents aged 3 to 18 years, including 179 with physical disabilities. Each subject was tested at 30 test stations, where 72 variables were measured relating to mobility, reach, strength, and size.

Results—Our findings show that, as expected, the physical capabilities of disabled young people aged 3 to 18 years are significantly less than the capabilities of disabled adults and able-bodied young people of the same age. Design data obtained are the results achieved by the

most able 80% of subjects in each age and disability group. A range of detailed guidelines was obtained which now enable building designers to take into account the needs of young people with physical disabilities.

Implications—The significance of this research is that a body of empirical data now exists for determining the design requirements for access to buildings for young people with physical disabilities. It is proposed that standards be developed which lead to improved access to the built environment for these people. The Standards Association of Australia is incorporating these research results in the draft of Australian Standard "Design for Access and Mobility, Part 3: Requirements for Children and Adolescents."

Recent Publications Resulting from This Research

Ergonomic Design for Physically Disabled Children, Parts 1 & 2.
Bails JH, Seeger BR. Kilkenny, Australia: Regency Park Centre, 1990.

Ergonomic Building Design for Physically Disabled Young People.
Seeger BR, Bails JH, Assist Technol (in press).

[222] Development of an Infant Crib to be Used by Physically Disabled Parents

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Sponsor: *Royal Ottawa Health Care Group*

Purpose—The objective of this project is to develop a crib that is easily accessible by a wheelchair-bound or otherwise physically disabled parent. Our specific goals are: 1) to make a crib that is easily accessible to a parent in a wheelchair; 2) redesign the main opening on the crib so that it is easy for wheelchair-bound persons to put the infant into the crib, and take the infant out; and, 3) ensure that all government regulations for cribs are fully met, and that the crib is perfectly safe for both infant and user.

Progress—A prototype crib is being tried out by three families with infants where one of the parents is physically disabled. The disabled parents find it invaluable, and we are proceeding with our efforts to have the crib marketed. In the meantime, we are introducing design changes which should broaden the market for the crib to include able-bodied users.

[223] Development of Systems to Enable Physically Disabled Persons to Board Inter-City Buses

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Sponsor: *Transportation Development Centre, Transport Canada*

Purpose—The purpose of this project was to design systems which would enable disabled persons to board (and therefore travel on) inter-city buses.

Progress—Two methods to enable physically disabled persons board inter-city buses have been developed. Full-scale operational mock-ups have been built of both systems. Tests on the mock-ups have shown that production versions of either system could be used to bring disabled persons into buses. A fully portable boarding system which could be carried in the luggage compartment of the bus would be a useful addition to the systems already designed and developed by us. The bus-boarding contract was awarded by Transport Canada in 1988, and has been successfully completed. A final report has been published by Transport Canada.

Results—We refined several parameters of the bus-boarding process: 1) boarding is best achieved by having the disabled client transfer to a special boarding chair prior to being brought into the bus. This transfer can be done at any convenient location in the bus terminal; 2) a boarding system should bring the special chair (with its

occupant) into the bus and place it beside the first row of seats: a level transfer can then be made if the armrest of the first row of seats can be pivoted upwards; and, 3) due to the confined space at the entrance to a bus, as well as the bus aisle, a boarding system must be designed that does not take up space which would otherwise be occupied by the client during boarding.

The two systems tested by us are designed to be based at a bus station. One of the systems uses an electrically-powered stair-lift to bring the transfer chair (with the client) into the bus. In addition to needing electric power, two operators are required for this process. The second system uses a manual ramp to bring the transfer chair into the bus. This is a relatively bulky system, but only one operator is required and no electric power is used.

While our two bus-boarding systems will work very well in the stations in which they are installed, neither boarding nor deboarding can be done in bus stations not equipped with these systems, nor in emergency situations away from a bus terminal. For this reason, we are advocating that a third and fully portable system be developed. Such a system, which was described in conceptual form

in a report for Transport Canada in 1987, could be stored in the luggage compartment of the bus and could be deployed by a single operator when needed. Other future developments may include the construction of operational prototypes of our original two systems.

B. Robotics

[224] Clinical Evaluation of a Vocational Desktop Robotic Aid for Severely Physically Disabled Individuals

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B239-2RA); Rehabilitation R&D Center Core Funds; VA Spinal Cord Injury Center*

Purpose—There are over 67,500 quadriplegics in the United States today, with an estimated 2,400 to 4,000 new injuries resulting in quadriplegia each year. These injuries occur most frequently to young males, and they can expect to live a relatively normal life span. Of these individuals, less than 12% are employed. Computer technology can provide a measure of independence for disabled individuals and is a fast-growing field of employment for the disabled; however, computers alone fail to address the manipulation needs of individuals who have no use of their arms and legs. In order to address this need for independence in the worksite and to provide a vocational tool for severely physically disabled persons, a vocational desktop robotic assistant (DeVAR-IV) has been developed, and is currently undergoing evaluation at the worksites of disabled individuals employed in the computer field.

Progress—In August 1989 we installed a DeVAR system in the office of a programmer in a local company. He has used the robot on a daily basis for four 10-hour days per week. Under voice control, DeVAR has been programmed to complete 10 tasks, including feeding lunch and medication, handling routine telephone dialing and answering, sorting office papers, arranging printer output on a copystand, handling fanfold computer print-outs, handing the person a mouthstick, and offering him a drink.

Results—A 2-week study to compare performance between an attendant and a robot completing the same desktop tasks was completed in the summer of 1989. Data

Recent Publications Resulting from This Research

Evaluation of Two Station-Based Boarding Systems for Inter-City Buses. O'Riain MD. Montreal: Transportation Development Centre, Transport Canada (in press).

analysis is ongoing and will be reported in the coming year. Preliminary results indicate that there is a difference in completion times between the attendant and the robot for the desktop tasks, but that this has minimal effect on job productivity given the nature of the tasks and robot usage.

Implications—In conclusion, although a robot entails a significant capital investment for the employer or employee, the maintenance costs are minimal compared to the continuing costs of hiring an attendant for 40 hours per week and of retraining new attendants (on the average, three to five new attendants hired per year). A \$50,000 to \$100,000 system can be expected to pay for itself in about 3 years. The process of transferring the technology to the private sector has been started and is expected to lead to timely product introduction.

Recent Publications Resulting from This Research

Clinical Evaluation of a Desktop Robotic Assistant. Hammel JM et al., *J Rehabil Res Dev* 26(3):1-16, 1989.

Design and Evaluation of a Vocational Desktop Robot. Van der Loos HFM et al., in *Proceedings of the 12th Annual RESNA Conference*, New Orleans, 107-108, 1989.

Designing Rehabilitation Robots as Household and Office Equipment. Van der Loos HFM, Hammel JM, in *Proceedings of the International Conference on Rehabilitation Robotics, A.I. DuPont Rehabilitation Research Institute*, Wilmington, DE, 1990.

Field Evaluation of a Robot Workstation for Quadriplegic Office Workers. Van der Loos HFM et al., *CARDIOSTIM 90 Conference*, Nice, France, 1990.

A Voice-Controlled Robot System as a Quadriplegic Programmer's Assistant. Van der Loos HFM et al., in *Proceedings of the 13th Annual RESNA Conference*, Washington, DC, 129-130, 1990.

[225] High Speed Obstacle Avoidance (Mobile Autonomous Robot Base for Rehabilitation Applications): A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #B989-PA)

Purpose—The purpose of this pilot study is to implement a high speed obstacle avoidance system on a Denning DRV-1W Robot. This system will allow the robot to travel at normal walking speeds and automatically steer around obstacles in its path, with little or no slowing. The basic technique employed was developed within the scope of an independent research project focusing on mobile robot applications in hazardous environments. This pilot study will implement the obstacle avoidance algorithms on the Denning robot in a form which can be integrated with companion tracking and global travel subsystems.

Methodology—The Denning robot has a built-in ring of 24 ultrasonic sensors which supply the raw detection data used by the software. By sampling distance data from these sensors at a rapid rate, the obstacle avoidance software can build and continuously update a real-time map of the environment, including both stationary and moving objects. The heart of the system is the "Virtual Field Histogram" algorithm, which uses the information within the map to plan platform movements in real time, allowing the robot to reach a desired final location while avoiding collisions along the way.

Results—During the last year, the on-board 68000 computer has been replaced with a 20 MHz 80386. This allows existing obstacle avoidance software (written in the C programming language) to be ported from another research robot to the Denning platform used in this pilot study. The ring of ultrasonic transducers present in the Denning has been interfaced to the main 80386 over a high-speed serial link. Initially, this serial link and others already present in the Denning were a source of frequent internal communication problems. These problems have been corrected by switching from RS-232 to RS-422 serial communication.

The obstacle avoidance software has been ported to the Denning robot. Modifications necessary to operate

this software with Denning hardware are largely completed, and testing and optimization of the algorithm has recently begun. Several safety features have been added to prepare the platform for increased autonomy during testing. These include a remote-operated kill switch and a built-in watchdog timer circuit.

Future Plans—The obstacle avoidance algorithm being used in this project was initially developed using a Cybermation K2A mobile robot combined with a custom-designed ultrasonic ranging system. This custom sonar system was designed to provide several specialized functions not presently available with the commercial Denning ultrasonic system. To allow the Denning to take full advantage of the sonar mapping algorithms, it will be necessary to add these features to the Denning sonar system. This will be accomplished by altering the device driver software supplied by Denning with the platform. Once this is accomplished, future work will include the integration of the obstacle avoidance subsystem with the companion tracking and global travel systems described in accompanying reports.

Recent Publications Resulting from This Research

- Mobile Robot System for Rehabilitation Applications. Levine SP et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 185-186, 1989.
- Semi-Autonomous Mobile Robot Platform for Rehabilitation Applications. Levine SP et al., in Proceedings of the International Advance Robotics Programme First Workshop on Domestic Robots and Second Workshop on Medical and Healthcare Robotics, United Kingdom Department of Trade and Industry, 15-18, 1989.
- Fail-Safe Features of a Mobile Robotic Platform. Jaros LA et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 291-292, 1990.
- Ultrasonic Sensor System for Mobile Robot Obstacle Avoidance and Navigation. Borenstein J, Levine SP, Koren Y in Proceedings of the 1990 International Conference on Rehabilitation Robotics, A.I. DuPont Institute, 121-131, 1990.

[226] Global Travel (Mobile Autonomous Robot Base for Rehabilitation Applications): A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #B990-PA)

Purpose—A mobile robot must be able to plan a path in order to travel from one point in an environment to another. However, even in fairly well-structured environments, unexpected objects can obstruct a robot's pre-planned path. In such cases, in addition to employing local obstacle avoidance capabilities to circumnavigate unexpected objects, the robot may need to plan an alternative path to the required destination.

This pilot study entails the implementation of a global travel system designed to work in conjunction with an obstacle avoidance system. The system includes a path planner as well as an infrared (IR) beacon system for determining absolute position. These systems are intended to allow a mobile robot to store information about the environment in a "world model," and then compute (or recompute) optimal paths in order to navigate within dynamic environments.

Methodology—The global path-planning algorithm being developed is an enhancement of the A* algorithm and is being integrated with the previously developed local obstacle avoidance algorithm already present on this robot. The integration allows for the mutual use of the world model information so that information gathered by the local obstacle avoidance system is made available to the global path planner whenever it is invoked. In this way, a path to the desired target location can be planned which takes into account all the known information as well as any unexpected obstacle information that may have been observed by the robot in its travels.

The absolute positioning system uses a commercially available IR beacon system from Denning, which consists of a rotating IR detector mounted on the robot and coded beacons which are fixed at known locations throughout the environment. By spotting three of these from one location, the absolute position of the robot can be triangulated.

Results—A new triangulation algorithm has been developed which allows for greater flexibility in the placement of the beacons and automatically finds the precession as well as the position of the robot. Our research has also

shown that the current beam width of the Denning beacons (approximately 10 degrees) is too narrow; they are being modified in order to increase the area from which they can be seen. Additionally, improvements in absolute positioning are being further investigated in terms of using the correlation of sensor information with information stored in the world map (such as the location of walls). As part of this research, a method to determine the relative quality of the maps created by the sonar data has been developed.

Future Plans/Implications—We plan to completely integrate the absolute positioning, global path-planning, and local obstacle avoidance systems on the Denning DRV-1W robot as part of this 1-year pilot project. This will include the ability to detect "trap" or other unexpected conditions (such as a closed door) in the local obstacle avoidance mode and automatically invoke the global path planner when required. Similarly, the local obstacle avoidance mode will automatically deviate from the suggested global path if unforeseen obstructions are encountered.

In parallel with this integration, we plan on further enhancing the global path-planning algorithm to take into account very large environments. This will require the development of high-speed map simplification (data reduction) routines for efficient memory storage and recall.

Recent Publications Resulting from This Research

Dynamic Path Planning for Mobile Robot Real-Time Navigation. Zhao Y, BeMent SL, Borenstein J, in Proceedings of IASTED International Symposium Robotics and Manufacturing, 162-166, 1989.

Mobile Robot System for Rehabilitation Applications. Levine SP et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 185-186, 1989.

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[227] Companion Tracking (Mobile Autonomous Robot Base for Rehabilitation Applications): A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #B99I-PA)

Purpose—The purpose of this pilot study is to design, develop, and implement a nonphysical link between a robot (Denning DRV-IW mobile robot) and a user-companion. This system will allow the robot to autonomously follow or guide the user. It will integrate sensor information from several subsystems and generate robot movement commands to cause the mobile platform to follow the companion automatically. The goal of the pilot study tracking system is to reliably follow a companion in the laboratory setting, maintaining a follow distance of 0.5 to 2.0 m, even with other individuals crossing between the robot and companion.

Methodology—The tracking system under development depends on two sensor systems. The first is based on an infrared (IR) detector capable of measuring the direction to a coded IR beacon. The detector is mounted on the mobile platform and can accurately calculate the direction to individual beacons. With one or more beacons placed on the robot's companion (e.g., on a belt), the robot can use the IR detector to uniquely identify the direction of the companion from among all objects present in the operating environment.

The second sensor system involved in tracking is a ring of 24 ultrasonic sensors mounted in a ring around the platform. This ring measures the distance from the robot to the nearest obstacle in each of the 24 circular directions. This information is primarily used by the obstacle avoidance system to control robot motion. However, it will also be used to measure the distance between the robot and its companion.

Results—The two sensor systems are now operational. The ultrasonic detector ring is working properly to supply

distance information for both obstacle avoidance and for companion tracking. The IR detection system is able to identify direction and calculate absolute position within the environment. However, the beacons supplied with the IR system are too large and too directional to be effectively worn by the companion. Therefore, the beacon is being redesigned so that it can be mounted unobtrusively on a piece of clothing and will be able to disperse its beam through a much wider angle.

Future Plans—The main task remaining for this 1-year pilot study is to integrate the raw data coming from ultrasonic and IR detectors into a coherent picture of the relative locations of the robot and companion. The companion tracking system has been designed so that data from both of these sensors are integrated into the same map used for obstacle avoidance and global travel. From this map the robot will need to calculate and execute the movement commands necessary to allow the mobile platform to follow the companion. Movement commands will be edited by the obstacle avoidance software which is already running on the platform.

Recent Publications Resulting from This Research

Mobile Robot System for Rehabilitation Applications. Levine SP et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 185-186, 1989.

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Ultrasonic Sensor System for Mobile Robot Obstacle Avoidance and Navigation. Borenstein J, Levine SP, Koren Y in Proceedings of the 1990 International Conference on Rehabilitation Robotics, A.I. DuPont Institute, 121-131, 1990.

[228] Rehabilitation Robotics Research at King's College, London

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Sponsor: *None listed*

Purpose/Methodology—Research within the Information Engineering Research Group at King's College, London has been directed at the development of a Telethesis Control System known as TASK FORCE. This software drives an RTX robot arm in a workstation environment and runs on any PC-compatible computer using a single switch input. The emphasis of the research lies in the provision of a low-cost aid requiring minimal operating skill for high-level quadriplegics. Robotic aids have traditionally been controlled in a motion-specific manner by directing the position of the end-effector within a particular coordinate frame. In order to reduce the cognitive demands on the user, TASK FORCE provides task-specific control of the telethesis. Single-object transfers of the form "Move Object A onto Shelf B" are combined with more manipulative functions to perform complex tasks. This system provides greater flexibility than preprogrammed systems and requires no trajectory training phase. Task Planning is achieved using efficient collision avoidance algorithms which interrogate a simple environmental model.

Progress/Results—Over the past year, TASK FORCE has been refined through an iterative series of user trials and procedural modifications. Evaluation of the system has taken place at both a residential center for adults and a school for teenage children. Most recently, volunteers have been asked to complete a coffee-making task using

a water dispenser and a miniature water boiler. Many users expressed doubt as to their ability to carry out such a task, but all achieved some degree of success.

The teenage children involved in the trials were able to adapt to the new technology more rapidly than the adults. Many of the younger users had gained considerable experience with word processing software at the school and therefore adapted to the hierarchical menus presented on the computer monitor with ease. Mistakes in the use of the control system were generally caused by a lack of concentration rather than a misunderstanding of the user interface.

The trials have demonstrated the way in which motion-specific and task-specific control concepts may be integrated under a common user interface in such a way as to obscure the inherent differences between the two approaches. Users appeared to be unaware that they had switched between the various modes of operation because their concentration was on the task itself.

Recent Publications Resulting from This Research

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Task Planning Strategies for the RTX Robot Arm. Dallaway JL, in Proceedings of the International Conference on Rehabilitation Robotics, 1990.

Task Specific Control of a Robotic Aid for Disabled People. Dallaway JL, Tollyfield AJ, J Microcomput Appl (accepted for publication).

[229] Human-Machine Interaction via the Transfer of Power and Information Signals

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Sponsor: *National Science Foundation*

Purpose—Robot manipulators perform tasks which otherwise would be performed by humans. However, robot manipulators often fail to achieve performance comparable to human performance. For example, humans excel at avoiding obstacles, assembling complex parts, and picking up fragile objects. In physical (mechanical) strength, robots can outperform humans. If robot mechanical

strength could be integrated with human physical strength under the control of the human intellect, we would have an intelligent, strong, maneuvering device for a variety of tasks.

Extenders are devices worn by humans which increase human mechanical ability, while the human intellect serves as the central intelligent control system

for manipulating the extender. Commands are transferred to the extender via the contact forces between the human and the extender, eliminating the need for a joystick, push-button, or keyboard to transfer such commands. The operator becomes an integral part of the extender while executing the task. When the human uses the extender to touch and manipulate an object, the extender transfers to the human arm, as natural feedback, a scaled-down value of the actual external load which the extender is manipulating: the human "feels" the external forces in the manipulations. Thus, extenders can be used to maneuver heavy loads with greater dexterity, speed, and precision. In many situations, extenders can replace fork-lifts.

Workers frequently maneuver objects manually without the assistance of any lifting devices. When a worker maneuvers an object with the assistance of an extender, the worker endures smaller forces, and consequently suffers fewer work-related injuries.

Considering these advantages, two large markets for the extender technology can be identified: 1) work situations in which objects weighing less than 400 lbs must be lifted in spaces where fork-lifts and similar devices cannot operate; and, 2) work situations in which objects weighing less than 50 lbs (e.g., baggage) are lifted by workers manually without the help of any lifting devices: although workers can lift such objects manually, the frequent repetitive maneuvering of such objects often causes injuries.

Progress—To develop and test nonlinear control algorithms, a direct-drive, electronically-powered extender was built. The direct connection of the motors to the links (without any transmission systems) produces highly nonlinear behavior in the extender. This extender has two degrees-of-freedom corresponding to a shoulder and an elbow. Two motors are located at the same height as the average human shoulder. Force sensors are located at the

human-extender and extender-load interfaces. A third degree-of-freedom may be added: either rotation about a vertical axis or roll about a horizontal fore-aft axis.

Accomplishments include: 1) nonlinear stability analysis and the trade-offs between stability and performance for extenders with nonlinear behavior; 2) the nonlinear control algorithm that creates force amplification over amplification over a wide frequency range; 3) a set of experimentally-verified mathematical ground rules for controllers of general robotics worn by humans (e.g., orthoses for disabled people); 4) the feasibility of using electric actuators for high-speed maneuvers of small loads (i.e., less than 50 lb); 5) the trade-offs between stability and performance (i.e., force implication); 6) the role of human dynamics in the control of the extender system; 7) a stable control algorithm which creates robustness in the presence of human impedance variations; and, 8) a stable adaptive control algorithm which creates uniform performance in the presence of load variations.

Recent Publications Resulting from This Research

- On the Stability of the Human/Machine Interaction. Kazerooni H et al., NASA Conference on Space Telerobotics, Pasadena, CA, 1989.
- On the Stability of Robotic Systems Worn by Humans. Kazerooni H, Foslien WK, American Control Conference, Pittsburgh, 1989.
- On the Trade-offs Between Stability and Performance in Human-Machine Interaction. Kazerooni H, IEEE Conference on Systems, Man and Cybernetics, Boston, 1989.
- Force Augmentation in Human-Robot Interaction. Kazerooni H, Mahoney SL, American Control Conference, San Diego, 1990.
- Human-Robot Interaction via the Transfer of Power and Information Signals. Kazerooni H, IEEE Transactions on Systems and Cybernetics 20(2), 1990.
- Stability and Performance of Robotic Systems Worn by Humans. Kazerooni H, IEEE International Conference on Robotics and Automation, Cincinnati, 1990.

Awards

- The O. Hugo Schuck 1989 Best Paper Award, American Control Conference. Awarded in May 1990.

[230] Development of Semiautonomous Control for the UT/HMRC Robotic Aid

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Sponsor: Natural Sciences and Engineering Research Council of Canada; Canadian Paraplegic Association

Purpose—The purpose of this project is to develop a semiautonomous control system within a general purpose

robotic aid for high-level quadriplegics. This system will offer the flexibility of adapting the robotic aid to an

unstructured environment, while avoiding a heavy control burden on the user.

The first specific goal is to implement a semi-autonomous control strategy in software with the following control attributes: 1) instructability—to allow the definition of new objects and locations within the workspace, and to allow user-defined tasks; 2) repeatability—to allow repetition of user-defined tasks; 3) adaptability—to allow the system to adapt to a non-rigid environment; and, 4) modularity—to allow the replacement of variables that constitute a learned task in order to perform a functionally different task, but of similar primitive behavior.

The second specific goal is to compare the functional benefit of the semiautonomous control strategy with more traditional control strategies.

In the domain of technical aids for the handicapped, much research has been directed at transferring robotics technology to physically disabled persons with the goal of providing them with autonomy. With the advances made in robotics and computer technology, it is now possible to allow a high-level quadriplegic to partially manipulate the environment with limited external assistance. Our present efforts are directed at developing a semiautonomous system which incorporates the flexibility of direct control and the ease of use of a workstation into a single system.

Methodology—Primitive Commands: A set of primitive commands that address the needs of this population will be defined. Needs will be determined through a review of the literature. Tasks will be categorized and delineated to obtain the essential primitives to perform a set of desired tasks.

Implementation: In order to attain the control attributes, the following software components will be addressed: trajectory generation, environmental attributes, data structures, and user interface. The system will be implemented on a UMI RTX manipulator, controlled by an IBM PC/AT-compatible computer. A VOTAN speech recognition unit will be provided for user input. Three infrared proximity sensors, mounted on the robot's gripper, provide the feedback required by the automatic grasping algorithm.

Clinical Testing: Testing will consist of asking the user to perform specified tasks after training. The tasks will be designed to take full advantage of the semiautonomous control system. The user will also perform these tasks using the more traditional direct control approach. A questionnaire will be administered after each test. This

questionnaire will be designed to measure users' attitudes and opinions toward the control strategies.

Results—A preliminary set of primitive commands has been developed. These commands comprise three categories: 1) variable-dependent (e.g., GO TO location, GET object, MOVE object TO location, where "object" and "location" are variables which can be defined by the user); 2) direct control (e.g., forward, elbow left, down); and, 3) time-dependent (e.g., WAIT).

The four control attributes were achieved by allowing the system to operate in two modes: "LEARN" and "REPEAT."

Instructability and *Repeatability* are implemented by allowing the user to guide the manipulator through a desired task using the primitive commands available. Once completed, the entire sequence of steps and all variables that constitute the task are saved in memory under a new task name. This procedure is possible in LEARN mode. When a task has been instructed and saved, the user switches to REPEAT mode. In this mode, all tasks previously defined under LEARN mode can now be invoked. When an object or location is unknown to the system, the user switches to LEARN mode and guides the manipulator using direct control primitives to teach the necessary parameters.

Adaptability was achieved with an internal model that represents objects and locations. Associations with their names are updated as the environment is altered.

Modularity can be illustrated with the following simple example: in LEARN mode, the user has defined the task DRINK as:

MOVE milk TO mouth

WAIT

MOVE milk TO counter

In REPEAT mode, the user reissues DRINK.

The system responds by showing the sequence of primitives that constitute DRINK and the variables previously associated with it (milk, mouth, counter). At this point the user can either accept the default values or substitute "milk" with "pop," and "counter" with "shelf," as long as these variables have been taught using the appropriate provision. This illustrates the strength of this method in its ability to modularize tasks.

Future Plans/Implications—Formal clinical evaluation of the system will be conducted upon completion of the aforementioned implementation. We anticipate a considerable reduction in the control burden on the user.

[231] Design and Implementation of a Rehabilitation Robotics Programming Environment

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Sponsor: Nemours Foundation

Purpose—The Programming Environment Project seeks to address the need for a standardized rehabilitation robotics programming environment. Designed for the professional robotics programmer, this environment would include all of the basic software and hardware tools necessary for minimizing the engineering effort involved in developing a specific clinical or research application. This development falls into three broad development areas. First, the design of a standard software interface to provide communication between the computer and the robotic manipulator. Second, the design of a standard software interface to provide communication between a user and the computer via a variety of input devices. Finally, the selection of, and where necessary, the development of programming utilities useful to a research of applications development environment. This project also serves as the technical support project for the Rehabilitation Robotics Research Program at the Alfred I. duPont Institute.

Progress—The previous year has seen the development of a prototype control library implemented on the RTX robot. The library consists of three levels of access to the robot: motor-space, joint-space, and reference frame-space. Three reference frames have been implemented in open-loop: Task-Oriented, Base, and Tool. Documentation for Version 1.0 of the library is complete.

An objects data structure (C-library) has been created and documented. This library allows for the management of abstract *objects* in space. Documentation is currently in progress. Both the objects library and the robot library use a common data structure to represent position information. Preliminary tests using small, specialized applications and either keyboard, joystick, or powerglove input, indicate that the library will function as predicted and provide a powerful interface and programming environment.

Future Plans—The 1991 project year will include testing and evaluation of the existing software, and expansion of the project into a number of new areas:

Field test developed software. Software developed in the first year and a half of the project will be tested in both internal and external research projects. Internal

projects will include the Hybrid Force/Position, Human Interface, and Analog Control projects. External projects will include Ohio State and Cambridge Universities.

Investigation of closed-loop control. Robot control is currently functioning open-loop. Closed-loop control has the potential for providing more accurate control, but requires implementation of error correction capabilities. The resulting code will need to be evaluated and compared with the open-loop approach for accuracy and stability.

Implementation of the robot library on a second robot. The Manus robot will be available in the early part of 1991 and will be the second robot on which the control model will be implemented. Manus is a wheelchair-mounted system designed specifically for rehabilitation applications. Given the flexibility of its environment, Manus is ideally suited to direct control and will serve as a powerful test of the modularity and effectiveness of the robot control architecture.

Development of an input device architecture. The architecture must be possessed of a number of features. Application code must be able to access the specified input device in a standard way, and must be able to dynamically select from implemented device drivers.

Utility development (graphics and reference). Development of programming utilities will consist of two parts: 1) the project survey will be completed and programming tools extracted from the survey will be assembled in a reference document and disseminated at both the RESNA and ICORR '91 conferences; and, 2) the use of graphics as both a programming tool (i.e., robot simulation), and an interface tool (i.e., feedback and control), will be evaluated and the necessary software tools developed.

Recent Publications Resulting from This Research

- Development of a Programming Environment for Rehabilitation Robotics. Gilbert M et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 377-378, 1989.
- RTX Robot Control Library: Straight Line Motion. Caruso J, Gilbert M, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 329-330, 1990.
- A Software Tool for Manipulating Objects in Space. Gray J, Gilbert M, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 121-122, 1990.

[232] Task-Oriented Hybrid Force/Position Control

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Sponsor: Nemours Foundation

Purpose—This project proposes to research and develop strategies for robot compliance using a hybrid of force sensing and position control.

Progress—The RTX manipulator is being used in this project. In the first year, the position aspect of the hybrid control has been investigated. A kinematic and velocity solution of the RTX has been derived. This solution was programmed in the C language and forms the nucleus of the control algorithm.

Hybrid force and position control has not been achieved as of yet. A passive compliance was added to the end effector to provide a constant force of contact with the task surface.

Methodology—The use of a robot manipulator as an assistive device for a person with disabilities introduces issues of safety and compliant control which are the focus of this project. In such an environment, the manipulator will be needed to perform tasks which require intimate contact with the person and motion control which complies with the environment (i.e., shaving, feeding, etc.). Force sensors present on the robot arm will detect force-of-contact with objects. Strategies will be developed to utilize this force information interactively so as to achieve compliant control.

Preliminary Results—The kinematic and velocity solutions have resulted in a novel control algorithm for the RTX which has application across other manipulator systems. The initial solution utilized a virtual four-bar linkage as a constraint for the links of the RTX. The result was the ability to control the velocity of the tip of the end effector to move about the surface of a sphere while maintaining its orientation directed towards the center of the sphere. This motion is referred to as Target Centered Control and, in addition, reduced the number of degrees of freedom required to control this motion to just two.

The key to the solution is that the reference axes are located in the center of the virtual task sphere. The commands related to the robot are in terms of the task being performed, not in terms of the required motion of the

robot. In this way, an individual may concentrate on performing a task. Eventually, the manipulator will become transparent.

An entire joystick-driven control model has been developed for the RTX based on this approach of task-based minimum degree-of-freedom commands. Task-Oriented Control enables an individual to point the RTX hand at an object, move towards the object, orient about the object, grasp it, and move it to some other location using similar movements. All inputs to the control model are in terms of the task.

Future Plans—The Task-Oriented Control model will be examined in terms of its efficiency and applicability to certain tasks. A number of studies will be performed to determine the extent of task-based control axes. In addition, partitioning and pairing of task axes will be examined to determine appropriate 2-degree-of-freedom task relationships.

The active control of the force exerted by the robot manipulator will be investigated. This Hybrid Force/Position control will be demonstrated on a specially constructed two-link manipulator. Upon successful completion of this device, an active unit will be designed and attached to the end effector.

Appropriate control interfaces will be investigated to match the abilities of a targeted population of disabled users. Not all disabled users of a robot manipulator will be able to control a joystick. Other controllable gestures, such as the motion of the shoulders, or of the head, will need to be identified and evaluated.

Recent Publications Resulting from This Research

- Controlling a Telethesis to Perform Tasks. Crochetiere WJ, 1990 International Conference on Rehabilitation Robotics Conference Papers, Wilmington, DE, 1990.
- Task-Oriented Control of a Robot Manipulator. Mahoney RM, Masters thesis, Drexel University, 1990.
- Task-Oriented Control of a Robot Manipulator. Part I: The Concept. Crochetiere WJ, Mahoney RM, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 299-300, 1990.
- Task-Oriented Control of a Robot Manipulator. Part II: Implementation on the RTX. Mahoney RM, Crochetiere WJ, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 289-290, 1990.

[233] Design of a Small Compliant Robot for Children

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Sponsor: *Nemours Foundation*

Purpose—Rehabilitation robotics has traditionally looked for complex solutions to the task of giving a person with quadriplegia independence. The common thread in all these projects is to give the robot the same functionality as a human arm (a very remarkable machine designed over several million years). This project proposes a much simpler system based on giving a robot similar functionality to a head-stick and providing force as well as visual feedback for the user. Employing this approach, the user will have a simpler robot that will break down less often. The user will become more effective, and build a strong internal representation of the robot's capabilities.

Most rehabilitation robots are complex, having 5 or 6 degrees-of-freedom. This is understandable given that to grasp an object from an arbitrary orientation requires at least 6 degrees-of-freedom. However, it is difficult to provide the user with a full level of control for a rehabilitation robot of such sophistication because it demands a high level of intellectual ability in the user, or expensive and as yet unrealized technology in the robot. In comparison, although head-sticks are ugly, they provide a person with considerable influence over his or her environment with only 2-degrees-of-freedom.

The proposed project will develop a simple robotic device that can be mounted on a wheelchair laptray. It will have similar functionality to a head-stick, but will operate over a wider volume, not tire the person using it, or cause the obstruction typical of a normal head-stick.

Progress—Several design criteria have already been fixed, the most important of which is the use of a pneumatic drive for the power source. Although a pneumatic drive has several undesirable control characteristics such

as a high degree of hysteresis, the advantage is the built-in compliance, a necessary feature for safety in interactive robotic design.

Methodology—Two prototype systems will be developed. The first is a kinematic prototype that will allow us to evaluate design configurations, the control problem, and a pneumatic system of actuation. This will be constructed using the facilities of the Applied Science and Engineering Laboratories.

A functional prototype will be designed as a result of the information that emerges from the kinematic prototype. This robot will be fully operational and will be manufactured by a third party. While the functional prototype is under construction, the project will investigate Cartesian closed-loop control and suitable interfaces to the robot.

A major aim of this project is to design with safety issues in mind. Many safety issues are not resolved in rehabilitation robotics and it is hoped that this project will be a demonstration of safe design by ensuring fault tolerance and predictable modes of failure. The United Kingdom Department of Trade and Industry has begun setting up safety guidelines for interactive robotic systems; the U.S. will have to begin a similar process in the near future.

Future Plans—The short-term benefits are to see how a simple robot can best be used to assist a person with a physical disability, and to evaluate the safety design criteria that are involved. The long-term benefits are to promote the sense of independence for children with disability, by providing a direct means of interaction with the environment.

[234] Quantification of the Effective Manual Dexterity Skills of Users of Rehabilitation Robotics Systems

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Purpose—Robot manipulators have shown great promise as assistive devices for the disabled. Many methods have been developed to enable an individual to control a manipulator to aid in manipulation of his or her environment. However, no standardized approach has been provided which allows for a quantitative evaluation of these methods.

This project proposes the development of a standard test which will enable a quantitative assessment of the effective manual dexterity of a rehabilitation robot. The effective manual dexterity of a rehabilitation robotics system is defined as those manipulation skills an individual exhibits while controlling the system interactively to perform dexterous tasks.

The test will be independent of the manipulator being used, the input device driving the manipulator, and the level of disability of the user. The test will be based on standard tests which are currently being used in the field of occupational therapy. In this way, comparisons may be made between existing norms.

Progress—Several standard tests of human manual dexterity skills have been identified. The tests chosen are applicable because they involve testing the skills of one hand. These tests are the Jebsen Hand Test, the Minnesota Manual Dexterity Test, and the Box and Blocks Test.

Methodology—The overall objective is the development of a standard test which will assess the effective manual dexterity skills of an interactively controlled manipulator. Subtasks required to achieve this goal are: 1) investigation of existing tests of human motor function: current tests which are used in the field of occupational therapy to assess the level of manual dexterity skills will be inves-

tigated. Occupational therapists will be the main resource; 2) determination of the applicability of these tests to a rehabilitation manipulator: once a set of tests has been identified, they will be considered in terms of their ability to provide reasonable data if used to evaluate the "manual dexterity" of a manipulator. If appropriate, the tests will be used as is. If not appropriate, modification to the test will be considered, which may increase its applicability; and, 3) administration of the test: once the details of the tests have been finalized, actual tests will be carried out in order to compile a base data set and test the reasonableness of the test. These trials will be carried out with able-bodied persons using a to-be-determined level of control.

Preliminary Results—This project is currently in the planning stage and no significant results have been achieved as of yet.

Future Plans/Implications—The investigators intend to investigate the developed test as a research tool in the rehabilitation robotics field. There are several areas where this test may be applicable.

It may be possible to develop a relationship between scores obtained on this test and the ability of an individual to perform ADL tasks using a rehabilitation robotics system. In the same way, an individual's progress with the system may be monitored by administering the test at significant intervals. It may also be possible to use the scores from this test to evaluate and compare different aspects of one system.

Ultimately, the testing scheme which may result from this project could form an integral part of the overall assessment and evaluation of rehabilitation robotics systems.

[235] Quantitative Evaluation of Voice-Controlled Robotic Manipulation for Rehabilitation Purposes

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Sponsor: Office of Special Education Programs, U.S. Department of Education

Purpose—A voice-controlled vocational robotic workstation known as VoiceMOVES was developed to suit the vocational needs of individuals with motor disabilities. A user-intuitive human-machine interface which functions as a voice-commanded robot programming language was designed, implemented, and tested. The interface was designed to enable the technically nontrained individual to customize and command a robotic manipulator. Although many qualitative accounts of various approaches in rehabilitative robotics exists, very few adequate quantitative assessments of human productivity have been proposed. The purpose of this study was to evaluate the feasibility of having technically nontrained individuals learn how to program a robotic manipulator and evaluate the accuracy and efficiency of the robotic system that we developed.

Methodology—VoiceMOVES incorporates a Universal Machine Intelligence RTX robotic manipulator and a Kurzweil Voice System 1000 word recognizer. An expert system manages the user's dialogue with the programmable robotic manipulator and speech recognizer. A knowledge base is maintained that contains a model of the robot's world by associating sequences of motions with phrases the speech recognizer accepts. The system functions as a Robot Motion Editor, allowing the user to edit the knowledge base.

Results—Eight subjects were trained to use VoiceMOVES. Four of the subjects were technically literate. The other four were technically naive. Each subject received over 30 hours of experience with VoiceMOVES. A subject's performance was analyzed with respect to the time it

took to complete a task. Three tasks were studied: manipulation of a cup, a tissue, and a book. Voice recognition accuracy and robot motion planning time were analyzed. A preliminary evaluation of the results indicate that there was no difference in performance between the technically trained and technically naive subjects. These results indicate that a robotic workstation which allows end-users to customize the robot motions is an effective design for a rehabilitation robotic workstation. Users can learn to safely and effectively pilot a robot manipulator. An approach which allows end-user programming of a robot is expected to be more cost-effective, minimizing the need for technical support from an engineer.

Recent Publications Resulting from This Research

- Design of a Human-Machine Interface of a Voice-Controlled Vocational Robotic Workstation. Horowitz DM, Hausdorff JM, in Proceedings of the 12th Annual RESNA Conference, New Orleans, LA, 117-118, 1989.
- Discussant Response. Horowitz DM, Hausdorff JM, in Proceedings of the First International Conference on Rehabilitative Robotics, A.I. duPont Institute, Wilmington, DE, 1989.
- Sensory Feedback and Automated Grasping for a Vocational Workstation. Hausdorff JM, Horowitz DM, Carroll SS, in Proceedings of the 12th Annual RESNA Conference, New Orleans, LA, 183-184, 1989.
- The Structure and Function of a Speech Control Language for Text Processing and Robotic Control. Horowitz DM, Hausdorff JM, in Proceedings of the 11th Annual International IEEE/EMBS Conference, Seattle, WA, 1757-1797, 1989.
- A User-Intuitive Speech Control Language for Text Processing and Robotic Task Planning. Horowitz DM, Hausdorff JM, J Am Voice I/O Soc 6:28-46, 1989.
- Preliminary Evaluation of a Voice-Controlled Robotic Workstation. Hausdorff JM, Quintin E, Horowitz DM, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 125-126, 1990.

[236] Rehabilitation Robotics/Man-Machine Interface Laboratory

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Sponsor: *Texas Department of Mental Health and Mental Retardation; National Aeronautics and Space Administration; Texas Advanced Technology Research Program*

Purpose—This research involves the development of a real-time, flexible control system for rehabilitation/assistive robots for use by disabled individuals. The control system is based on both voice recognition capabilities and an infrared sensor system placed within the robot grippers. This system is designed to augment menu-based, fixed-task robot functions by providing flexible motion and gripping controls for instances where preprogrammed tasks are inappropriate. This would include tasks that are not on the preprogrammed menu or emergency settings where rapid, flexible controls are required.

Progress—The voice recognition system is based upon modified commercial systems, including those by Dragon Systems and Votan Voice Systems. Recent research in voice recognition for a disabled population has centered on the ability of such systems to recognize slurred speech common to many disabled individuals with poor motor and vocalization skills. In addition, several methods to analyze and subtract ambient noise have been studied in order to optimize the voice recognition system design. Methods to integrate a flexible, voice activation system into other menu-driven, fixed-task systems have also been analyzed. The infrared sensor system has been designed and tested to provide automatic gripping of nearby objects. This function is elicited by a single voice command and produces a gripping function of both stationary and moving objects. A neural network control system is being analyzed to incorporate both voice and infrared data into a robot motion/gripper control scheme.

Results—The voice recognition system has been tested for a wide variety of speech abnormalities and accents. The commercially based systems have been modified to incorporate several speech classifications resulting from various disabilities. Several sources of ambient noise have been analyzed for amplitude and frequency content. Various electronic and computational noise cancellation

procedures have been developed as integral components of the modified voice recognition system. The infrared gripper control system has been designed, constructed, and tested on several types of small robots. Initial tests have demonstrated the ability to grip objects up to 18 inches from the gripper for both static and moving targets. The gripper system consists of many infrared emitters and receivers that determine the location and range of the target and controls the robot motion and gripping function to grasp the nearest object.

Future Plans/Implications—The voice recognition component to the overall robot control system is to be analyzed for potential integration with existing fixed-task, preprogrammed robot controllers in development at other rehabilitation research centers. The infrared gripper system will be tested for a wide variety of ambient conditions including light, target color and shape, target motion, and range from target to gripper. A neural network control algorithm is being continually studied to optimize robot motion and gripping function. The overall goal is to develop a flexible control system which can serve as an adjunct to fixed-task systems. The flexible version is being developed to allow disabled individuals and their assistive robots to cope with emergency situations where preprogrammed tasks cannot provide adequate support.

Recent Publications Resulting from This Research

- Analysis of Voice Processing for the Control of Devices to Aid the Disabled. Miller GE, Etter BD, Bartholomew JC, in Proceedings of the 12th Annual RESNA Conference, New Orleans, 410-411, 1989.
- Automated Grasping Aided by Optoelectronic Sensors. Etter BD, Duck MR, Seaman RL, IEEE Transactions on Robotics and Automation, 1990.
- Man-Machine Interfaces for the Disabled. Miller GE, in Advances of Bioengineering, Proceedings of ASME Winter Annual Meeting, 1990.
- Voice Controls for Manufacturing Environments. Etter BD, Miller GE, Manufacturing Review 2(4):242-249, 1990.

C. Communication Methods and Systems

[237] Computer Keyboard Emulation Through Interpretation of Pointing Gestures

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Sponsor: *Bloorview Children's Hospital Foundation*

Purpose—A new keyboard emulator is being developed for people with severe motor impairments. The objective has been to have the system imitate a human listener in an augmentative communication setting. The motivation is that previous successful human/machine interfaces (i.e., the mouse), have been based on some metaphor with another activity in which its intended users have had experience (in this case, face-to-face communication with another person through a direct selection communication board).

Methodology—For the system to imitate a human listener, it must be able to track and interpret pointing gestures. An infrared CCD camera-based tracking system has been converted to track a single retroreflective marker which the user typically wears on the fingertip. The sensor is mounted directly above the communication board and reports the marker position in two dimensions at a rate of 30 samples per second. The position information is communicated to an IBM PS/2 Model 30 286. The user's selection set is printed on the communication board and the location of the center of each element (e.g., letters, combinations, commands, etc.) is stored on the PS/2.

The system is being designed to collect and use information in two distinct areas. The first area is the patterns of characters the user typically enters. A Markov Model produces a probability distribution for the next character to be entered. The probability distribution is used to lower the acceptance standards for elements that would seem probable and make unlikely characters correspondingly more difficult to enter. A dictionary tree structure is maintained in the system for automatic completion of words with those unique endings that the user has entered in the past.

The second area of customization involves trajectories taken in the targeting motions that lead to the selection of communication elements. The technique is based on a connectionist pattern associator using an error

back-propagation learning rule and normalized exponential output units. Sets of position samples from labeled trajectories are used in a training phase to customize the associator to the user's qualities of motion. After training, when a new trajectory is input, the system responds with a probability distribution for destination. Experimentation is in progress (with this general arrangement) with a nonimpaired subject, and an associator has been trained that can predict destination correctly in 72% of the training cases.

Preliminary Results—Early experimentation has shown the importance of automatic customization to the qualities of a particular user. The study involved two persons with motor impairments to the degree that they use a direct selection letter board for communication with another person. The participants were shown several messages on a television screen, which they were instructed to communicate to another person using their letter boards. In half of the trials, the listener was someone with whom the person regularly communicated, and who was familiar with the qualities of the communication process. In the other half, the listener was a stranger. Messages could either be a series of random characters or a complete sentence. For the sentences, the familiar listener could interpret the gestures as much as twice as quickly as the unfamiliar listener. For the random character strings, the results were less distinguishable. The results support the idea that a system which can gain long-term experience serving a particular user will be more successful than a generic, static design.

Future Plans—Future work will focus on the combination of these two areas of customization into an overall system capable of making realistic predictions of the next element that a given user intends to communicate. A single-subject study is planned, using a crossover design to compare the user's net rate of input with this system, with that of the user's prescribed written-communication device.

[238] Computer Interpretation of Gestures Made by the Severely Disabled

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Sponsor: *Dundee University*

Purpose—Our purpose is to investigate free arm movement or gestural control of computer-based aids by the severely disabled. People with disabilities have problems producing discrete movement (e.g., hitting a switch), or serial movement tasks (e.g., pointing) necessary for the control of computer-based aids. In an attempt to overcome these problems, we intend to harness the repertoire of arm movements (or gestures) available to a particular subject. Computer recognition of the different gestures available to each subject will allow control of computer systems via gestures and remove or reduce the problems inherent in some conventional input systems.

Progress—Work is ongoing to develop a computer-based gesture recognition system.

Methodology—Examples of arm gestures have been collected from a number of subjects using a commercially available position-monitoring device. No restriction was placed on the types of movements that could be made by the subject. The movements were collected over a period of a few weeks, and recorded on computer. A number of examples of each movement type that the subject could perform were recorded during each session.

Signal processing and pattern recognition techniques will be used to analyze and classify each different movement that was made.

Results/Future Plans—Work is ongoing, with future plans for development of a real-time gesture recognition system and evaluation of its usefulness as an access methodology.

[239] A Blackboard Expert System Approach Toward Implementing an Adaptive Force Joystick Computer Input Device for the Tremor Disabled

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Sponsor: *Easter Seal Research Institute of Ontario*

Purpose—The long-term goal of this project is to develop expert system software which will help disabled persons to configure and maintain proper settings on their computer input devices on a daily basis. The short-term goal has focused on screen-based tracking tasks performed by persons with tremor disability using a force joystick input device. We believe this to be a good starting point for the adaptive problem due to the day-to-day variation in tracking ability which can occur with this population. The force joystick provides a solid anchor point for the tremor-affected hand and can be used to filter tremor using digital filtering routines.

One problem that arises when trying to perform any adaptive actions is that of how to define tracking performance such that the "goodness" of tracking has meaning. A second problem is that of selecting the proper joystick parameters so that performance is best with respect to tradeoffs between accuracy of tracking, speed, effort, tremor level, and other more vague properties such as

joystick "feel." Any successful adaptive interface must address these problems and it is here that the current research is focused.

Methodology—There are different viewpoints that can be taken when considering how tracking performance should be defined and measured in order to determine the force joystick parameters which result in good tracking. These viewpoints range from an expert therapist's qualitative assessments to employing various computer-based numerical measures. Each viewpoint results in a different performance assessment and associated proper joystick filter setting: the proper filter settings across the different viewpoints form a fuzzy set.

A study of how to combine the information to reduce the fuzziness in the solution is currently being conducted. Four different viewpoints of handling the tracking performance problem—knowledge source (KSs), are being used together in a blackboard expert system framework.

Knowledge sharing between the various KSs can occur at different blackboard levels and between different combinations of KSs. The level at which KSs share knowledge affects the degree of fuzziness in the resulting performance evaluations and filter parameters sets. The KSs in use within the framework are: 1) ARMA modeling; 2) spectral analysis; 3) a potpourri of operational definitions of performance; and, 4) an expert therapist's evaluation.

Progress—A blackboard expert system has been written in LPA MacProlog 3.1 using the FLEX expert system toolkit. Numerical processing routines were written in Lightspeed Pascal 3.0 and linked into the blackboard as Prolog predicates. The expert system runs on Macintosh II

and the screen tracking tasks run on a Macintosh SE/30 which is networked to the expert system over TOPS. To date, a simple pilot study has been conducted on three tremor-disabled subjects and five nontremor subjects.

Results—The pilot study results have shown that each KS can evaluate tracking performance and determine joystick gains independently with varying degrees of success.

Recent Publications Resulting from This Research

A Blackboard Knowledge-Based Approach Towards Implementing and Adaptive Force Joystick Computer Input Device for Persons with Tremor Disability. McGill RA, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 431-432, 1990.

[240] Formation and Modification of Attitudes Toward Young Augmentative Communication Device Users

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Sponsor: *Easter Seal Research Institute of Ontario*

Purpose—The attitudes which nondisabled speakers hold toward teenage and young adult nonspeakers who use augmentative and alternative communication (AAC) assistive devices to communicate may strongly influence the opportunities of such users. This investigation is designed to determine if the various ways assistive devices deliver messages influence the attitudes of non-disabled speakers. A method for improving attitudes is also being investigated.

Methodology—The project is comprised of two studies. The first seeks to determine if the type of conversational

relationship which able-bodied speakers have with a young AAC device user affects the attitudes of the able-bodied speakers. The second study seeks to determine the effects of four different outputs on the attitudes of the able-bodied speakers toward the AAC users. The second study also tests the use of a simple method for improving such attitudes. Both studies employ similar procedures.

Results—The results of the relationship study will determine the extent of the external validity of the output study.

[241] A New Approach to Augmentative Communication Services with Synergy Between a Central Resource of Expertise and Community-Based Programs: A. Implementation

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Sponsor: *National Health Research and Development Programme, Department of Health and Welfare, Canada*

Purpose—This project proposes a model of service delivery which attempts to address the conflicting demands of a centralized "center of excellence" approach with the needs for community involvement

and support. The proposed model is offered as a potentially generalizable model for the delivery of rehabilitation services and other long-term health related services.

The model is based on several key principles, including: more focused intervention; development of local resources; increased empowerment of local personnel; increased independence of consumers; reduction of waiting list; and, increased job satisfaction for staff.

Methodology—Many aspects of the service delivery model outlined in this proposal will be implemented on a 2-year pilot basis through resources available at the Augmentative Communication Service (ACS) of the Hugh MacMillan Rehabilitation Centre. The program evaluation component of this project will be conducted through the leadership of an independent evaluator. The evaluation component has been submitted as a companion proposal to allow for process as well as outcome evaluation approaches.

Preliminary Results—A new model of service delivery has been developed in an attempt to build on the strengths of the existing model, and to address the following key issues: 1) more focused, and therefore more effective, intervention. Allowing staff to work with a fixed number of clients per year will allow ACS staff to focus their energies to provide more effective intervention rather than doing a little for many clients. The set period of intervention time (e.g., one year), as opposed to the previous open-

ended time line, will allow better planning and organization of assessment and intervention goals; 2) development of local resources. Stronger links with the community will provide clients with the community-based services essential to successful integration into local environments; 3) greater empowerment of facilitators and local professional teams. The intensive instruction of facilitators and local teams carried out gradually over a long period of time will be much more effective in terms of providing them with the skills and information required to become more informed participants in the rehabilitation process; 4) increased independence for users and families in terms of deciding what level of intervention is appropriate at various times in their family life. Eventual reduction of the dependency of users on major health care agencies and training in self-advocacy are seen as potential long-term goals; 5) impact on the waiting list. This model will allow ACS to minimize the waiting list and to accelerate provision of services for clients who previously may have waited up to 2 years for service; and, 6) greater job satisfaction. The concept of seeing progress over a definite period of time relative to realistic goals will decrease frustration of staff who feel they can "never do enough."

To address these key issues, the new model will be implemented for a 2-year period with a view to evaluating its effectiveness.

[242] A New Approach to Augmentative Communication Services with Synergy Between a Central Resource of Expertise and Community-Based Programs:

B. Evaluation

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Sponsor: National Health Research and Development Programme, Department of Health and Welfare, Canada

Purpose—The purpose of this project is to evaluate the new ACS model of Service delivery (see "A New Approach to Augmentative Communication Services with Synergy Between a Central Resource of Expertise and Community-Based Programs: A. Implementation," p. 192).

Methodology—The proposed evaluation of the new ACS model of service delivery will take advantage of an information-collection system already in place within the department. In addition, two other data-gathering instruments will be developed specifically for the evaluation.

The approach will comprise both a process and an outcome evaluation. Input will be provided from all three groups involved with the service: 1) service consumers and/or their parents and facilitators; 2) ACS service provision staff; 3) Level 1 and 2 augmentative communication clinic personnel (authorized by the Assistive Devices Program).

The focus of the evaluation will be on examining the items which prompted the development and introduction of the new service delivery model, in particular those listed under the goals of the new service delivery model: 1) effectiveness of intervention; 2) development of local

resources; 3) greater empowerment of facilitators and local professional teams; 4) increased independence for users and families; 5) impact on the waiting list; and, 6) greater job satisfaction for ACS staff.

Progress—Specific preimplementation data have already been, or are currently being collected, and will provide the baseline information for the evaluation.

[243] Development of a Universal Communication Aid: LUCY

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Sponsor: *Innovative Research Programme for the Disabled/Aids for the Handicapped; Foundation for the Development of Communication Aids for the Handicapped; OSKAR; Lions Club, Delft; Ministry of Social Affairs*

Purpose—The overall purpose of this project is to develop and realize a universal communication aid for a broad class of disabled people. Therefore, starting with the Lightspot-Operated Typewriter (LOT), designed especially for quadriplegics, a new communication system, called LUCY, was developed. Presently, LUCY functions as a replacement for a PC-keyboard, as well as a control device for a standard PC-printer or speech synthesizer.

Methodology—LUCY consists of a panel with a height of 236 mm and a width of 282 mm, representing a character display and a matrix of 8×11 cells. With the help of the cells, the user can select one of the characters and send it to one of the above-mentioned devices. LUCY can be used in two different control modes: as a matrix communicator, and a direct lightspot selector.

When used as a single-switch matrix communicator, the rows light up one by one. When a row containing the character to be selected lights up, the switch must be activated. Next, the cells in the row light up one by one. The desired character can be selected by activating the switch again when the corresponding cell lights up.

When using LUCY as a lightspot-operated system, the input device consists of a light pointer which can be mounted on a pair of spectacles. The light pointer gener-

ates a red spot on the panel, and the character is selected by exposing a cell for a user-adjustable time. The lightspot detection unit is only sensitive to modulated red light from the light pointer, so the system can be used even in a highly illuminated room.

The character generated is sent to either a personal computer or the character display. When using a printer or speech synthesizer, the user can edit the characters in the display, and send the text to the output device when the sentence is completed.

Progress—This year, the prototype of LUCY was further developed so that it is now commercially available (Shannon Electronics, Zoetermeer, The Netherlands).

Future Plans/Implications—In the future, other input devices will be available. The main advantage of this communication aid is its flexibility. The possibility of selecting different input and output devices creates the opportunity to use LUCY in numerous applications, from recreative purposes up to professional computer usage in industry. This flexibility also makes it possible to adapt LUCY to all stages of any degenerating disease, so that the patient can use LUCY first as a lightspot-operated device, and later as a matrix communicator.

[244] Speech Synthesis Program

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Sponsor: *National Institute on Disability and Rehabilitation Research; Nemours Foundation*

Purpose—The purpose of this program is to create high quality, unrestricted, multilingual synthesized speech in a number of different voices.

Methodology—This program can be partitioned into four projects. These are: 1) development of a software diphone synthesizer; 2) development of an automatic diphone

extractor; 3) generation of a bilingual speech synthesis system based on English and Spanish; and, 4) production of a hardware speech synthesizer.

The software synthesizer will use diphones as its units of synthesis because diphones allow unrestricted vocabulary while providing high quality, intelligible speech. Diphones are speech segments that run from the steady state of one phoneme to the steady state of another, capturing the transition between phonemes. The diphones are recorded in carrier words and then manually extracted and stored. The process of creating a complete library takes approximately 6 months.

Once the library has been completed, it must be used in conjunction with an algorithm that converts written text to synthesized speech. This text-to-speech algorithm is used in conjunction with an algorithm that partitions text into syllables with stress markers. With this information, pitch contours can be imposed upon the synthesized utterance. This increases its intelligibility and naturalness.

In order to create a synthesizer that allows the voice of choice, an automatic diphone extractor is being developed. The automatic extractor uses the original library for template matching, plus rules based on the spectral analysis of the recorded speech. With it, a nonvocal person will be able to choose the voice and dialect with which he/she wishes to communicate.

To further extend the population of nonvocal users, a bilingual speech synthesizer is being developed. This project includes the development of a Spanish text-to-speech algorithm using Spanish phonemes, the creation of an inventory of Spanish diphones, and the development of a set of rules for syllabifying Spanish words. The final subproject is the development of a hardware speech

synthesizer. This hardware synthesizer must be portable, lightweight, flexible, and efficient.

Preliminary Results—Currently, a speech synthesizer with a child's voice is being developed. The text-to-speech algorithm has been updated, and is undergoing final corrections. The automatic extractor functions well with a number of phonemic combinations. Work is now being done with a new method of extraction that should yield higher quality results. Rules for a Spanish text-to-speech algorithm have been completed, as well as rules for syllabifying Spanish words. Currently, a Spanish inventory is being developed.

Future Plans—Future plans include final work on the text-to-speech algorithm, along with further development of the syllabifier, the completion of the automatic diphone extractor to allow for the creation of a number of different synthesized voices, the completion of a Spanish synthesized voice, and the production of the hardware diphone synthesizer.

Recent Publications Resulting from This Research

- New Methods for Pitch Change During Time-Domain Waveform Coded Diphone Speech Synthesis. Yarrington D, Jones M, Foulds RA, in Proceedings of the 12th Annual RESNA Conference, New Orleans, LA, 220-221, 1989.
- The Synthesis of High Quality, Human Sounding Speech. Yarrington D, in Official Proceedings of Medical Applications of Voice Response Technology, Pittsburgh, PA, 1989.
- Improvements in Synthesized Speech Using Time-Domain Waveform Coded Diphones. Yarrington D, Schlemmer J, Foulds RA, in Proceedings of the 1990 AVIOS Conference (in press).
- Personalizing Voices for Non-Vocal Individuals. Yarrington D, Tritin P, Beam F, Commun Outlook 12(1) (in press).

[245] Personal Computer-Based Augmentative Communication Systems

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Purpose—The purpose of this project is to develop prototype personal computer (PC)-based augmentative communication systems. The PC-based approach allows more flexibility, configurability, and ease of updating.

Progress—A PC-based communication system, named Meta4, has been designed for use with desktop or laptop

computers that support MS-DOS. In addition to the actual communication software, supporting utilities have been created to facilitate easy modification and customization of the system. At present, there are four utilities under development: 1) abbreviation/expansion utility; 2) vocabulary management utility; 3) configuration utility; and, 4) usage analysis utility.

Each utility is designed to make maintenance and updating of the system as simple as possible. They also provide a convenient interface to all the flexible features of Meta4.

The vocabulary management utility is a valuable addition to this package. This utility provides full flexibility in designing and maintaining a user's vocabulary set. Two features make this utility particularly user-friendly. First, the program utilizes a drop-down menu system used by many commercially available software packages. Second, the program presents the contents of the vocabulary set exactly as Meta4 does. This allows the vocabulary to be viewed in the same way they appear to the user. Both of these features are aimed at creating an interface that is familiar to the user, making the program easier to use.

One of the most unique features of Meta4 is its ability to track and analyze data. The program automatically records each selection made by a user. This information can later be analyzed using the support utility and can provide valuable insight into the efficiency with which the device is being used. This analysis can also guide the clinician or user in updating the system for the user's changing needs. At present, work is concentrating on the presentation of the data in ways that can be quickly and easily understood.

Preliminary Results—At this time, Meta4 is being used as a functional communication device for one test subject. This subject uses Meta4 on a Toshiba laptop computer for daily communication needs. Researchers on the project continue to be guided by the feedback from this subject.

— All of the support utilities have reached prototype form and work is continuing to refine their function and interface to the user.

Future Plans—Meta4 will soon be available for transfer out of the laboratory. Communication is continuing with manufacturers on the potential for Meta4 to be developed as a commercial product.

Recent Publications Resulting from This Research

Automatic Data Collection and Analysis in an Augmentative Communication System. Miller LJ, Demasco PW, Elkins RA, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 99-100, 1990.

A Human Factors Approach to Vocabulary Management for an Augmentative Communication Device. Rookard CJ, Thompson M, Mineo BA, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 101-102, 1990.

[246] Development of an AAC Software Architecture

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Sponsor: National Institute on Disability and Rehabilitation Research; Nemours Foundation

Purpose—The goal of the Architecture Project is to facilitate more cost-effective development of Augmentative and Alternative Communication (AAC) application software by developing a general framework for describing AAC systems and a supporting set of tools that will allow other developers to produce new applications. This will effectively minimize duplication of efforts in a field where resources are precious, and promote sharing of ideas and software among developers. By utilizing object-oriented software technology, it is possible to develop a set of building blocks that can be used to realize this goal.

Methodology—The use of object-oriented analysis, design, and development provide significant advantages toward reusable software. Specifically, we have chosen the C++ language for its elegant support of the OOP

paradigm, its efficiency, and for its wide availability in the marketplace.

Progress—The architecture under development consists of two major components. LASO (Library of Adaptable Software Objects) is a set of C++ class hierarchies. Each hierarchy represents a functional AAC system component. For example, the *Vocab* class supports a flexible vocabulary set structure. LASO has been designed to maintain maximum independence between class hierarchies. This allows developers to use as many or as few of the system components as desired.

The second major component of the architecture is the *Adapt* authoring language. This language, which is based on LOGO, provides three major functions. First it supplies a high-level approach to providing interconnections

between system components and provides an overall description of application function. Second, *Adapt* scripts can be associated with key activations to provide the user with a powerful command language. Finally, the script language could be used to implement unique selection methods.

Future Plans—We plan to continue design and development on both system components and hope to have a distributable release of the toolkit within the next year.

[247] Rate Enhancement Through Sentence Compansion

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Sponsor: *National Institute on Disability and Rehabilitation Research; Nemours Foundation*

Purpose—The goal of this project is to increase the communication rate of physically disabled individuals via natural language processing techniques. We wish to take as input a compressed message (i.e., uninflected content words) from the disabled individual, and yet pass a syntactically and semantically well-formed utterance to a speech synthesizer or text preparation system. At the same time, we wish to do this by placing as little a burden on the user as possible. Thus, we are not interested in a simple coding system where sentences have been stored and are indexed by their content words.

Progress—The present system has a vocabulary of over 400 words. It handles most tenses, produces a variety of sentence constructions, and has the capability to infer the verb or subject in some situations.

Methodology—Input to our system are the uninflected content words of an utterance; thus, many function words such as determiners (e.g., the, a) and prepositions (e.g., of, in) will be left out. The system is responsible for filling in missing words as well as correctly conjugating the verb and forming a syntactically correct utterance. We attempt to form an utterance whose word order most closely reflects the word order given in the original input the user wishes to convey. For example, if the system is given "APPLE EAT JOHN," we would like the system to produce the sentence, "THE APPLE IS EATEN BY JOHN." In order for the system to generate a well-formed

Recent Publications Resulting from This Research

- Adapt: An Authoring Language for a Flexible AAC Architecture. Ball JE, Demasco P, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 179-180, 1990.
- Determining Future Software Requirements for Augmentative Communication Systems. Demasco P et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 337-338, 1990.
- A Software Object Library for Augmentative Communication Systems. Demasco P, Ball JE, Kerly P, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 350-351, 1990.

utterance, it employs a semantic parser to form a semantic representation of the input words. In this example, the parser recognizes that EAT can be a verb which accepts an animate ACTOR and an inanimate/food OBJECT in order to correctly infer the semantic relationships between these input words. The resulting semantic representation (along with a specification of the original word order) is then passed to the translation component which is responsible for replacing the semantic terms with their language-specific instantiations. The final phase of the processing is a sentence generator which attempts to form a syntactically correct sentence that retains the general order of the original input words.

Future Plans—Areas for further improvement include allowing for more complex sentence constructions, a richer vocabulary, and making use of discourse information. In addition, we have recently begun a collaboration with a Semantic Compaction and Prentke Romich to transfer this technology into a "scaled-down" system.

Recent Publications Resulting from This Research

- Applying Natural Language Processing Techniques to Augmentative Communication Systems. McCoy K et al., in Proceedings of the 13th International Conference on Computational Linguistics, Helsinki, Finland, 413-415, 1990.
- A Domain Independent Semantic Parser for Compansion. McCoy K et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 187-188, 1990.

[248] A Force-Sensing Resistor Switch for Use by Handicapped Children

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Sponsor: *National Science Foundation*

Purpose—Single switches are often used by handicapped children to operate communication and educational aids, computers, environmental controls, and mobility aids. Severe motor-impaired students often have difficulty controlling the amount of force that is applied to such a switch. The result is a “wearing down” of the sensitivity of the switch. Other students, however, may not elicit an adequate amount of pressure to activate the switch. This points out the need for a pressure-sensing switch that can be adjusted to control the threshold force necessary to activate the switch. In this study, we have used a commercially available force-sensing resistor (FSR) to build such a switch.

Methodology—The FSR is a polymer film device that exhibits a decreasing resistance with increasing force that has been developed for several applications (one being human touch control). Due to the various characteristics of the FSR, as well as its small thickness (<0.5 mm),

these devices made by Intertink Electronics are available in a variety of shapes and sizes. We have built a circuit that allows the FSR to be used as a simple force-adjustable switch. The comparator circuit allows for the sensitivity of the switch to be adjusted to accommodate the specific needs of the child. This adjustment is done by adjusting a 20 K ohm potentiometer. As force is applied to the surface of the FSR, the voltage of the comparator decreases, and when the voltage at pin 9 reaches a value equal to or less than the present voltage, the relay is activated, turning the device on. Additional devices (such as a timer device) can be connected, or additional circuitry can be included in the device to facilitate added capabilities.

Results—The first force-sensing resistor switch was built with a small (15 mm diameter) FSR element. This has been used by a few normal volunteers and will soon be used by several motor-impaired students at the Caddo School for Exceptional Children.

[249] Development of Input Interfaces for Handicapped Children

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Sponsor: *National Science Foundation*

Purpose—This project has been initiated to design and implement a group of input modules (input interface devices) which will augment/assist the ability of a handicapped child in operating devices and/or systems to perform various tasks requiring single input(s). This work is part of a larger project to develop electronic devices to aid handicapped children.

Progress/Methodology—Based on investigations, some of the requirements for an interface device were that the device should be: 1) flexible (different sensor options for different needs and capabilities); 2) small and compact in size; 3) rugged; 4) able to interface with a variety of devices or systems; and, 5) easy to use without being restrictive to the child. There are few,

if any, commercially available devices that meet all of these requirements.

One of the first observations was that although some children could not consistently apply a specific amount of force to a switch, they usually could maintain a specific position. Using the capacitance of the body, it was possible to utilize a capacitive proximity device as an input sensor. A commercially available proximity device, obtained from a local manufacturer, performed satisfactorily in that the children were able to activate the switch reliably and with little difficulty. However, this switch was relatively expensive due to the industrial requirements which exceeded our needs; it also used an AC power supply which was not ideal for school use. This prompted us to design a proximity

device which would operate on batteries and be relatively inexpensive.

We also observed that each individual child appeared to be able to produce a particular activation force that they could consistently apply. Yet, most devices in use were designed for a single activation force. A switch with a variable activation force could be very advantageous. Such a switch was designed using a force-sensing resistor (FSR) which is an extremely thin (1 mm or less) sensor composed of a conductive polymer that changes resistance with force. In comparison to the microswitches normally used, the FSR could potentially be a much thinner switch with a large surface area, without the use of a lever or a large plate.

Results—The proximity device prototype, and the FSR prototype, have been in use at the Caddo School for Exceptional Children for nearly one year and have proven to be useful and advantageous. Additionally, information has been obtained from the field test leading to enhancements and improvements to the devices.

Future Plans—This is the first stage of a larger project to develop a family of devices which will allow for optimal interfacing between the child and the assistive device. One of the desirable requirements was wireless connection between the switch and the assistive device or system. Field-testing on an infrared wireless link is presently being completed. Along with other possible input methods, such as very thin (< 2 cm) tape switches, optical methods are presently being examined. Some of the circuits are being redesigned for incorporating features such as analog output and minimization of the supply current. Some basic studies are also being conducted to better understand the capacitive coupling between an area of the body and a metal plate.

Recent Publications Resulting from This Research

Design of Electronic Devices to Aid Handicapped Children.

Williams P, Saha S, in Proceedings of the Eighth Southern Biomedical Engineering Conference, 5-8, 1989.

[250] Switchless Selection Techniques Using a Headpointing Device

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Sponsor: *Natural Sciences and Engineering Research Council of Canada; University of Toronto*

Purpose—Our purpose was to investigate the use of simple head gestures to emulate the standard mouse buttons in a graphical user interface. Current graphical user interfaces often require selecting a character or a file by clicking a mouse button once. Double clicks are used to select a word or to start an application. Highlighting a phrase or moving a file is done by pushing and holding the mouse button while moving the mouse to the new position. This type of interface presents a barrier to many people with disabilities.

Specific objectives included: 1) demonstrating several gestural techniques for simulating mouse button selection methods without using external switches; 2) evaluating the techniques implemented and describing their advantages and disadvantages; and, 3) developing strategies and criteria for customizing the parameters of the different techniques in order to achieve good user performance and satisfaction.

Progress—People with good head control can use a headpointing device to emulate a mouse and move a

cursor about the screen. In order to make mouse button selections, external switches such as sip-and-puff or eyebrow switches can be used, but this is not an ideal solution. By using head gestures, it is possible to implement switchless selection methods. The measurable parameters of head gestures include pause time and the direction, duration, speed, and distance of movement. Combinations of these can be used to differentiate between intended selections.

The Long Range Optical Pointer (LROP), a headpointing input device originally developed at the Trace Research and Development Center, was modified to allow its use with a high resolution graphics display. Two switchless selection techniques were then developed using the modified LROP. These are the Multi-Level Pause technique and the Nod and Shake technique.

With the Multi-Level Pause technique, the user holds the pointer steady over the intended target to begin the selection. An initial pause causes a single mouse-button-down action to be simulated. This allows the user to drag the selected object. Pausing longer causes the mouse

button to be released, simulating a single click. A further pause simulates a double click. The dragging action can be over-ridden by the user with a separate configuration program.

The Nod and Shake technique also begins with an initial pause; however, with this technique a cursor clutch is set, causing the cursor to freeze on the display. The user can then nod in one of three directions to simulate a single left-button click, a double left-button click, or a single right-button click. To start the dragging action, the person can simply pause longer instead of nodding, similar to the Multi-Level Pause technique.

Preliminary Results/Future Plans—The two techniques have been used to control a commercially available paint-

ing program which requires the use of all of the mouse button actions described. The clients who have used the techniques have found them to be effective and useful.

Some training is necessary in order to use the Nod and Shake technique consistently. To facilitate this, a small training utility will be developed. Good feedback is required for the user to know what state the system is in. Since the current clicks and beeps can become confusing, a more interesting range of audio cues will be created.

Recent Publications Resulting from This Research

Two Switchless Selection Techniques Using a Headpointing Device for Graphical User Interfaces. Hamann G, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 439-440, 1990.

[251] Gestural Predictive Control Systems for Persons with Motor Impairments

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Sponsor: *Natural Sciences and Engineering Research Council of Canada*

Purpose—The letter board is a well-established means of communication between a person with motor impairment and another person. The motor impairments of a letter board user usually affect the ability to speak and write; however, communication with the letter board can be efficient and flexible. One common observation is that the experience of the listener in communicating with a given individual has a positive influence on the communication rate. The experienced listener appears to be able to employ information about the user (not available to the inexperienced listener), in order to make predictions regarding the user's destination on the letter board. A device which could play the role of that experienced listener could provide improved interpretive power to an inexperienced listener. In fact, such a device could possibly improve communication between the user and the most desperately inexperienced listener of all: the modern computer.

A system capable of gaining and using experience about the communicative qualities of a particular letter board user is to be developed and tested. Specifically, the system's ability to predict the user's next word from characteristics of motions across a letter board is to be the measure of its success.

Methodology—There are two main questions in need of answers before the objective can be reached: 1) How does

the experienced listener make predictions about the next character to be selected? That is, on what qualities of the process must the system gain experience to be able to make reliable predictions? and, 2) How can an electronic system be made capable of gaining experience about anything?

A study called "The Role of the Experienced Listener in Augmentative Communication Systems (RELACS)" is currently being conducted in the Motor Functions Laboratory. The purpose of the study is to determine what constitutes "experience" in communicating with a letter board user.

Messages for the user to communicate to the listener are shown to the user through a computer monitor behind the listener's head. A marker-based hand tracking system quantitatively records all of the user's hand motions for later analysis. The entire session is videotaped so that the listener can later give reasons for any predictions that were made during the communication process.

Progress—In response to the question of how a computer can be made capable of learning about the communication qualities of each user it encounters (which are expected to be widely different), the design of neural networks is being explored. The neural network is a development in artificial intelligence which has recently become capable of solving "real-world" problems in pattern recognition.

Implications—This is a very active and exciting area of research, and it is considered that the neural network has the potential to revolutionize computer access

for people with physical disabilities by providing the computer with the ability to learn about each situation in which it is placed.

[252] Mobility Training and Evaluation for the Home and School Environment

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Sponsor: Ontario Mental Health Foundation; Toshiba of Canada Ltd.

Purpose—Physically disabled persons who are cognitively delayed to the extent that they cannot use assistive devices because they do not understand the functions of switches are at a serious disadvantage. Their inability to control devices prevents them from benefitting directly from mobility or communication devices, and also reduces their opportunities to learn from the experiences that these devices afford. In an attempt to remediate this problem, a community (home or school) training program using switches and toys was designed for persons who are developmentally delayed.

Methodology—Students who are both physically and cognitively impaired, and their parents or teachers, are given a trainer unit, a Toshiba T1000 microcomputer, lap tray, and five toys to use at home or at school. The trainer unit and program are being evaluated with 16 subjects, ranging in age from 5 years 1 month to 20 years 6 months, with a mean age of 11.5 years (standard deviation 5.4). Intelligence levels are in the severe to profound retardation range. The evaluation uses a pre-post experimental design that also allows for the comparison of subjects against controls, and against their own pre-study clinic records.

Each subject receives a tray with five embedded switches, each with its own stimulus lights mounted adjacent to the switch. At the start of the training program, only one switch is exposed, and only one toy is connected. When the student completes 100 trials in either parent/teacher-guided or free-play sessions, he graduates to the next training step. In the second step, a second switch is uncovered and incorporated into the training program. Another 100 trials later the student graduates to Training Step 3, at which time the third switch is uncovered, allowing three toys to operate successively. A total of five steps are being used.

In order to help the students make the connection between making toys move and making one's wheelchair move, an intermediary step was introduced in which the participants used training trays and switches to control the movement of a powered wheelchair. The wheelchair-mounted training trays have five variable-position pressure switches with attached stimulus lights, and a remote switching box that allows the therapist to control the stimulus lights and switches on the tray individually. The switching device was designed so that only one switch could be active at a time. This tray is useful for generalization training sessions.

A communications program (PROCOMM) is used to review the progress of the client and change the program—via the modem—to the next training step. Data collected at home or school are downloaded to the Centre and analyzed to determine if the subjects are ready to move on to the next training stage.

Results—With the exception of six subjects, all subjects were on the Centre's active caseload and had been referred for a mobility assessment from 6 to 18 months prior to the start of the study. At the start of the study, subjects who were assessed 18 months ago were still not able to drive a wheelchair.

With 2 subjects withdrawn for medical reasons (surgery), 7 out of 14 subjects show improvement in their wheelchair driving performance. If the subjects continue to progress towards behavior reflected in mobility skills, it is expected that by month 12 at least one person will be ready for a prescription, and two will need several weeks of in-chair training before receiving their own chair. Another three or four will have reached the point of having mastered directional switches and will have learned how and when to stop. This amount of change for subjects who have shown virtually no progression for years is extremely encouraging.

Recent Publications Resulting from This Research

A Microcomputer-Aided Mobility Training Program for the Multiply Handicapped. Zanier D, McPhail P, Voelker S, Ment Retard Learn Disabil Bull 17(1):51-62, 1989.

A Training and Evaluation Tool for Remedial Cause and Effect Development. Snell E et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, 43-44, 1989.

[253] Guidelines for the Requirements of Computer-Based Systems to Accommodate Direct Manipulation as a Means of Alternate Access

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Sponsor: Ontario Ministry of Colleges and Universities; IBM Corporation; IBM Canada Ltd.

Purpose—The goal of this project was to determine appropriate alternative access techniques for computer control by severely physically disabled people in a direct manipulation environment. Instead of typing commands, the user indicates objects (icons, text, menus, and graphical objects) depicted on the screen and directly manipulates them with a pointing device such as a mouse.

Specific research objectives were to: 1) describe the problems that people with physical disabilities have within a direct manipulation environment; 2) propose and describe modifications to pointing devices and to the environment to improve accessibility; and, 3) to make recommendations for future systems that will support the techniques or modifications that are proposed.

Methodology—Most of the problems posed by direct manipulation relate to the physical demands of the pointing device. The use of a pointing device involves several physical tasks: moving the pointing device, clicking one or more buttons, dragging the pointing device while holding the button, and moving between the keyboard and pointing device. The user must therefore be able to move the pointing device with relatively fine continuous control and press the button, as well as do both at the same time.

Progress—Much of the first year of the project was devoted to gaining a deeper understanding of the significance of direct manipulation, defining problems that can occur with pointing devices, and developing software to test various skills related to manipulating objects on the computer screen. In the second year, specific modifications to several pointing devices were proposed and implemented. These were developed in an iterative process of clinical assessment, device modification, and objective evaluation within clinical trials involving seven

individuals with physical disabilities. These trials spread across approximately 20 sessions, each lasting 2 hours, in which modifications were made to refine the participants' use of various pointing devices. Four other persons participated in further trials in which alternative direct manipulation techniques for accessing a text editor were tested using a single switch as a means of input to the computer.

Results—Our investigation identified key problems associated with pointing devices, and we were able to address many of them. All participants in our investigation were able to perform direct manipulation tasks using some pointing device. Most of the necessary modifications were relatively superficial and easily achieved. In some instances, prototype developments were required to achieve some functions. Dragging was the most difficult of all direct manipulation operations. The most glaring problem, and one that was not resolved within this study, was the movement between a physical keyboard and a pointing device. This problem alone decreases the benefits of direct manipulation interface in applications that involve keyboard entry.

One idea under development is to allow users with severe physical disabilities to delegate tasks by selecting intelligent objects/processes in the computer which will carry out certain functions. Selection may be done with as little as a single switch and a scanning technique.

Recommended strategies for developers of future systems have been prepared, based upon the experience gained within the trials. Some are feasible with current graphical user interfaces, but many would require changes in the interface design. Implementation of even the most modest strategies would open up access to new groups of users.

Future Plans—Two new research projects have been initiated from this work. The first investigates the combined use of a head pointing input system and voice recognition as alternate input for direct manipulation. The second studies the integration of voice recognition and scanning alternate access systems.

Recent Publications Resulting from This Research

Direct Manipulation: Its Significance for People with Disabilities. Brownlow ND et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, LA, 244-245, 1989.

Direct Manipulation: Problems with Pointing Devices. Brownlow ND et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, LA, 246-247, 1989.

Accessible Graphical User Interfaces: Strategies for Developers. Brownlow ND et al., Toronto: Hugh MacMillan Rehabilitation Centre, 1990.

Direct Manipulation of Text by Scanning. Shein GF et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 147-148, 1990.

Don't Manipulate, Delegate! Brownlow ND et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 153-154, 1990.

Modification of Direct Manipulation Pointing Devices. Treviranus J et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 151-152, 1990.

A Software Environment for the Testing of Pointing Ability. Brownlow ND et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 149-150, 1990.

Pointing Devices for Direct Manipulation: Problems and Solutions. Treviranus J et al., J Assist Technol (in press).

[254] Development of a Light Pointer

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Sponsor: *The Rehabilitation Centre, Ottawa*

Purpose—Light pointers are used as a communication aid and to activate light-sensitive switches. A lightweight and energy-efficient model was designed. Research is ongoing to increase the useful range of the light beam.

Progress—The shell of a mini Mag Lite flashlight was redesigned. Lenses were added and the light bulb

was replaced with a high-intensity light-emitting diode. Batteries were put in a compartment that can be carried in a pocket. The light pointer weighs approximately 25 g and the useful range of the red beam is about 1.5 m. A new model is under development to increase its range.

[255] Extraordinary Computer/Human Operation

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Sponsor: *Science and Engineering Research Council*

Purpose—The aim of this research project is to develop an accessible office workstation for a disabled user. This includes investigating the various types of input and output devices that are currently available and can be used by a disabled user, and incorporating a selection of these in a workstation application, thereby increasing the bandwidth available to each user.

Features such as monitoring, inferencing, and prediction will be implemented into the system to improve the interaction between the disabled user and the application.

This research is being carried out in collaboration with an avionics company involved with the human/computer interaction problems faced by pilots in modern

aircraft, in the hope that there will be shared ideas and resources.

Progress—This project is still in its early stages. The progress so far has been to research and collect information on input and output devices currently available. Information is also being collected on knowledge base systems to investigate how features such as monitoring, inferencing, and prediction can be implemented.

Future Plans—Future plans are to develop a prototype of a high quality computer-based workstation which incorporates all of the above features.

[256] Development of a Voice Output Intelligent Communication Enhancement System (VOICES)

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Sponsor: Social Sciences and Humanities Research Council of Canada

Purpose—The purpose of this project is to design a communication aid which can use linguistic and semantic information to make intelligent guesses as to what the communicator intends to say, thus reducing the number of key activations necessary to produce grammatically correct speech.

Methodology—The project proposes a system (rather than a particular device) for creating communication aids tailored to each individual user. The main component of such a system is an inventory of about 3,000 symbols, each equipped with vocabulary items, and their associated grammar. The user, and people working with the user, will be given tools from the inventory provided,

which will make it easy to construct and modify the device to suit the user.

The system will be programmed on Macintosh computers in HyperCard. The portable Macintosh will be used since it is battery-powered and can be mounted on wheelchairs. The symbols that will be used are Blissymbols, which are efficiently stored, displayed, and printed on Macintosh computers by means of the BlissTemplate Font, a Macintosh font developed by Dr. Reich.

Future Plans—The first year of the project will be focused on creating the system, and the second year on testing with users, evaluating its use, and making modifications in light of what is learned.

[257] Modeling of Performance with Computer Access and Alternative Communication Systems

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Sponsor: University of Michigan Rehabilitation Engineering Program; University of Michigan Bioengineering Program

Purpose—This project explores the application of engineering modeling techniques to improve understanding of the user interface of augmentative communication and computer access systems. The goal of this work is to provide both developers and clinicians with a framework that can improve the development and delivery of alternative access systems. The long-term goal is to use the model to quantitatively predict user performance with these systems and simulate a large range of user and system characteristics. The modeling process also offers a valuable qualitative analysis, since it provides the opportunity to carefully analyze the interaction between the user and an alternative access system, under a wide range of conditions.

Progress—One modeling technique used extensively in the field of human-computer interaction, called the GOMS model (Goals, Operators, Methods, Selection

Rules), has been used for preliminary work. The model provides a comprehensive description of user performance based on system-specific parameters as well as the cognitive, perceptual, and motor capabilities of the user. The GOMS technique has been used to model three row/column letter scanning interfaces, two with some form of word prediction and one without, to gain a more rigorous understanding of how word prediction affects a user's performance.

Several software tools have been developed that will make it possible to perform model validation studies. These include: 1) a fully programmable word prediction module, to allow simulation of numerous existing word prediction techniques; 2) a stand-alone data collection utility that records the time and content of a user selection from either the word prediction module or any other RAM-resident keyboard emulation interface; and, 3) statistics utilities that generate a profile of the user's

performance using the raw data from the data collection utility, as well as information about the word prediction dictionary contents.

Preliminary Results—Preliminary results, based on model simulations for the three interfaces considered, suggest the possibility that word prediction interfaces, developed as a faster alternative to row/column letter scanning, may actually be less efficient than letter scanning in some situations.

In addition, preliminary model validation work has been performed in the clinical setting. Performance data for a single user of a row/column letter scanning system was collected over a period of two months and compared to theoretical predictions of performance based on a simple model of row/column scanning. The data agreed closely with the model predictions over a wide range of scanning timing parameters, providing support for the quantitative accuracy of the modeling technique.

Future Plans—A primary direction for future research is to collect data on the performance of subjects with a variety of alternative access methods (including word prediction systems), and compare it with the model predictions that have been developed. A number of modeling techniques, including the GOMS model, will be studied to determine those most suited to this application. Refinement of model descriptions and input parameters can then be made to improve model accuracy.

Recent Publications Resulting from This Research

Modeling of User Performance with Computer Access and Augmentative Communication Systems for Handicapped People. Horstmann HM, Levine SP, in Proceedings of the 11th Annual Meeting of the Cognitive Science Society, Ann Arbor, MI, 659-666, 1989.

Quantitative Modeling in Augmentative Communication—A Case Study. Horstmann HM, Levine SP, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 9-10, 1990.

Modeling of User Performance with Computer Access and Augmentative Communication Systems for Handicapped People. Horstmann HM, Levine SP, *Augment Alternat Commun* (in press).

D. Private and Public Programs

[258] Using Existing Databases to Analyze the Medicaid Personal Care Optional Benefit Service

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Sponsor: *U.S. Department of Health and Human Services*

Purpose—The goal of this project is to describe how the various states have designed personal assistance service (PAS) programs using funds under the Medicaid personal care services option (pc-option).

The specific objectives of this project are to: 1) provide a national aggregate overview and a state-by-state profile of all the Medicaid pc-option programs as of 1985 and 1989; 2) discern trends in the way states have used the pc-option from 1985-1989; 3) compare the similarities and differences between pc-option programs in the different states; 4) compare on an aggregate level the similarities and differences between the Medicaid pc-option programs and programs funded by the Medicaid Waiver, Title XX, Title III, state funds, and mixtures of federal funds; 5) ascertain the degree of flexibility states have had in designing their programs within the limits imposed by Section 42 CFR 440.170(f); and 6) “understand the factors that

influenced states’ policy choices with regard to program design and implementation—including decisions about participation, program size, target groups, definition of services, organization of service delivery system, etc.”

Methodology—The World Institute on Disability (WID) built on its 1985 survey of the universe of PAS programs in the U.S. by conducting a follow-up mail survey of previously interviewed programs as well as new ones. The 1985 data set and the new 1989 data set are being analyzed in order to compare programs by funding source. In addition, WID is conducting site visits to six states in order to address the knowledge gaps identified from the analysis of the quantitative data.

Preliminary Results—Results of the research are now being examined. They will include the following reports:

1) a descriptive profile of each pc-option program from 1984 and 1988 data; 2) an aggregate analysis of the pc-option programs; 3) a comparison of the pc-option aggregate profile to the profiles of programs funded by other funding streams; and, 4) reports of site visits.

Future Plans/Implications—The major outcome of this research will be to provide policymakers and planners on the national and state levels with the quality of informa-

tion needed to develop a comprehensive and effective PAS system. More specifically, this research will allow policymakers to gain a better understanding of how funding source mandates, along with state creativity, have shaped the various ways in which services are delivered.

Recent Publications Resulting from This Research

The Effect of Government Funding Source on Personal Assistance Programs: A Summary of 1985 National Survey Data. Litvak S, Kennedy J. Oakland: World Institute on Disability, 1990.

[259] Applicable Barrier-Free Concepts Adaptable to Modern Technology Developments

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Sponsor: Federal Ministry for Regional Planning, Building, and Urban Development

Purpose—Following the concept of a barrier-free society, the question was raised as to what extent modern technology can be adapted to support individual independence by evaluating functional application based on a human factor containing all ages, abilities, and disabilities.

This research, which will be finalized by March 1991, evaluates applicable modern technologies in various fields for use in barrier-free environments in order to improve independent living for the elderly and persons with disabilities.

This international investigation was launched to find solutions to improve integration and find alternatives to institutional care for the elderly, support research in the field of gerontology, and provide assistance for the development of independent living rehabilitation for the elderly.

At the same time, the investigation should suggest the level of acceptance for high-tech application by the elderly in the living environment and find ways and means to educate them with the goal of extended independence supported by modern technology.

Another major goal is the utilization of any type of modern construction and/or material technology to create barrier-free housing and urban development for all

people at comparable cost; buildings and environments which compensate for restrictions of age and disabilities, and are freely accessible at all levels, or are constructed with provisions for added improvements if needed.

This conceptional development is supported by a federally funded research and development program under the heading, "Age-Complimentary-Technology," meaning to support developments which are capable of increasing the self-sustained independent status of all people of all ages in their individual environment versus integration into institutional homes of any kind.

Progress—The investigators make use of all available data and information systems and have launched an extensive international mailing to various applicable industries, requesting product literature, which is being reviewed in detail. Suggested usable items or developments within the boundaries of this research are recorded, including pertinent pictures. Approximately 15,000 letters have been mailed.

Future Plans—The results will be discussed and conclusions offered. The final report will be published this summer.

[260] Development of a Collaborative Training and Job Placement Program in Computer-Aided Drafting

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Sponsor: *Massachusetts Rehabilitation Commission*

Purpose—Many individuals with severe disabilities possess the proper motivation and abilities to pursue gainful careers in engineering-related fields. Nevertheless, these vocational areas have been closed to individuals with severe disabilities. This program will research methods by which individuals with severe disabilities can achieve gainful employment. A comprehensive supported training and employment program in Computer-Aided Drafting (CAD) will include the identification and implementation of appropriate computer adaptations to allow individuals with severe disabilities access to a computer. A training curriculum will provide individuals with computer literacy and expertise in the operation of CAD software. Collaboration with state agencies will allow for the identification and involvement of affirmative action employers. It is anticipated that a vocational rehabilitation

model incorporating a career internship will result in gainful employment.

Progress—Eleven individuals referred to the Rehabilitation Engineering Program were evaluated, and four individuals were enrolled in the CAD training program. The CAD training is being conducted at Roxbury Community College, Boston, where these individuals have been integrated into the regular classroom activities. Social work services are provided to help both able-bodied and disabled students work together.

Implications—It is anticipated that the program will serve as a model for the integration of advanced rehabilitation services provided by tertiary care centers into long-term community-based vocational training programs.

[261] Development of a Parts Counter for Persons with Mental Retardation

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Wichita REC is a consortium of The Cerebral Palsy Research Foundation of Kansas (CPR) and The Wichita State University College of Engineering (WSU). It is mandated by its funding agency, the National Institute on Disability and Rehabilitation Research (NIDRR), with the enhancement of the vocational opportunities of persons with severe disabilities.

During 1986, the state of Kansas designated CPR as the sole rehabilitation engineering support entity for its Supported Employment Initiative program. Since that time, CPR staff have fabricated numerous assistive devices for work centers and businesses that employ people with cognitive disabilities.

CPR was approached in 1989 by a center in northeastern Kansas that had two clients employed in a counting and packaging operation. Counting and packaging parts is a common employment activity for persons with

cognitive disabilities. For most of these workers, this is a slow process with a high error rate. Unfortunately, many counting fixtures are very specific relative to the size and shape of a particular product and are, therefore, not very versatile. Counting scales calibrated for various-sized parts are available, but are expensive and difficult for persons with cognitive disabilities to operate.

Results—A parts counter has been designed that incorporates the following design criteria: 1) it was required to count parts that ranged in size from 1/8 inch to 1/2 inch in diameter; 2) it was required to count quantities ranging from 4 to 135; and, 3) the device had to be easy to understand and operate.

The concept of the counter is simple. Operators drop parts, one at a time, into a funnel which guides the parts between a pair of optical sensors, triggering a counting

circuit. The funnel gives the operator a large target to hit, enabling persons with poor eye-hand coordination to operate the counter. To allow for different size parts, the hole in the funnel was made large enough to accommodate the largest part. Funnel inserts were then made with smaller holes for smaller parts. Use of inserts ensure that the parts drop through the center of the optical beam.

To comply with the criteria of varying count quantities and simple operation, it was decided to use a comparator circuit in which the operator would enter the desired count on three thumbwheel switches. As parts drop through the funnel, the circuit compares the running count with the total count. When the number of parts equals the count on the switches, a red light is turned on. A reset button is used to reset the internal count to zero and turn off the red light. The process is then repeated,

or a new count is set. A yellow light was added to the circuit to indicate when the count was three less than the total, warning the operator to proceed slowly and watch for the red light.

One option considered was to use a tally counter that would increase as each part was dropped through the funnel. However, this requires a worker with a better understanding of numbers to keep a close watch on the count. It was decided that lights were more effective in increasing the vigilance of the operator. Another option would be a buzzer, for persons who are visually impaired.

When the parts counter was installed, there was a tendency to drop more than one part through the counter at a time. It was eliminated through training. Otherwise, cognitively disabled workers had no difficulty utilizing the counter.

[262] Rehabilitation Engineering Center on Service Delivery Models

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Center for Rehabilitation Technology Services (CRTS) is a rehabilitation engineering center (REC) supported by the National Institute on Disability and Rehabilitation Research (NIDRR), and operated as part of the South Carolina Vocational Rehabilitation Department. Under a cooperative agreement with NIDRR, the mission of the center is to demonstrate and disseminate innovative models for the delivery of cost-effective rehabilitation engineering services to assist in meeting the needs of, and addressing the barriers confronted by, individuals with disabilities. Within this broad mandate, the following scope of work has defined the parameters for CRTS' activities: 1) develop and test models of assistive technology service delivery systems; 2) evaluate the effectiveness of these models; 3) develop a model of statewide databases; 4) establish continuing education programs to provide accessible training; and, 5) develop and test training programs specifically designed to train volunteer technology counselors nationally. Through publications, presentations, and involvement in national initiatives, CRTS shares the results of its activities with individuals and organizations in the Southeast and across the United States.

Progress—CRTS has initiated a number of projects designed to address the above scope of work. The following is a list of current project titles: 1) Development of an Assistive Technology Information Resource Center (IRC); 2) Access Technology—Development of a Statewide Information and Referral (I&R) Service for Assistive Technology Applications; 3) Development of an Assistive Technology Demonstration Center (TDC); 4) Development of a Guide to Funding Resources for Assistive Technology in South Carolina; 5) Implementation of Regional Service Areas for Statewide Technology Access; 6) Development of a Primer of Assistive Technology Terminology; 7) The Utilization of a Facsimile Machine in Service Delivery: A Pilot Project; 8) A Survey of Rehabilitation Engineers Nationwide; 9) Symposium Series on Critical Issues Affecting Assistive Technology Services; 10) Utilization of Assistive Technology in the Vocational Evaluation Process; 11) Development of a Service Provider Directory; 12) Development of Planning Guides for Implementing Assistive Technology Services; and, 13) Training Materials for Assistive Technology Awareness.

Future Plans/Implications—The center is continuing to address critical issues affecting the distribution and

utilization of technology by persons with disabilities. Among the core areas of focus in upcoming activities are coding strategies and alternative methods of funding for assistive technology, information dissemination, training and qualifications of service providers, models of community service delivery, volunteer technology delivery, rural service delivery, universally designed products, and

technology and transition. CRTS welcomes input by persons and organizations nationwide on these and other service delivery issues.

The reader is encouraged to contact the center for more information on specific activities and for publication information.

[263] Operational Definition of Independence

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Purpose—This project is designed to develop an operational definition of independence that incorporates three dimensions of the term: perceptions of control over one's life, psychological factors, and behavioral or functional characteristics. The objective is to develop an assessment instrument to quantify an individual's independence in each of the above domains.

Progress—After extensive search of the literature and expert consultation, the Personal Independence Profile (PIP) was constructed to operationalize the consensus definition. The PIP consists of items measuring perceived control over one's life, selected from Flanagan's Quality of Life Domains; items from Fordyce's Independence Scale, which deals with psychological factors such as competitiveness, self-esteem, and group autonomy; and sections from the Arthritis Impact Measurement Scale (AIMS), a Guttman-type ordering of general functional ability items.

The next step in the development of the PIP was to conduct various tests of its validity. Two hundred subjects in 10 centers for independent living (CIL) across the country were sent the PIP, 120 of whom also completed questionnaires designed to measure the same or similar constructs to test the convergent validity of the PIP. In addition, CIL staff who knew the subjects well rated each person on a global rating scale. A sample of 185 of these 200 subjects produced data that were complete enough to enable cluster analysis of the PIP-Psychological Independence, PIP-Control, and PIP-Physical Independence scores.

Results—Responses from the initial 61 subjects surveyed were analyzed to test a model proposing that indepen-

dence of living arrangements, productivity, participation in leisure activities, and mobility would be antecedents of perceived control of an individual's life spheres, as well as that the severity of an individual's physical disability and level of income would directly affect these antecedents of control. Educational level was found to interact with living arrangements, productivity, and leisure activities to predict perceived control. Mobility, however, directly predicted degree of perceived control. The conventional wisdom that an interaction between physical ability and income would predict each antecedent of control was not supported. In future studies, other variables possibly affecting these antecedents, such as psychological self-sufficiency, will be explored.

Validity testing of the PIP resulted in Cronbach's alpha coefficients of 0.79 for psychological independence, 0.86 for control, and a range from 0.66 to 0.94 on the five subscales of the functional (AIMS) section. These results support the internal validity of all three constructs of the PIP. Reliability estimates of the five parts of the AIMS yielded coefficients of reproducibility from 0.87 to 0.93.

Cluster analysis of the three PIP scales from 185 subjects using Ward's minimum variance procedure yielded three salient clusters: 1) 81 subjects were identified as independently minded and relatively nondisabled; 2) 55 as nonindependently minded; and, 3) 49 as independently minded and relatively disabled. The first cluster demonstrated relatively average levels of psychological independence, tended to feel in control of things important to them, and had a relatively good physical status. The second cluster had relatively low levels of control over their lives and were unable or unwilling to take the initiative to make changes, but exhibited no common factors for physical independence. The third cluster exhibited

relatively high levels of psychological independence and control, but a high degree of physical impairment. This

last group was similar to the first group except for having more severe physical impairments.

[264] Evolution of Independent Living Programs: A Longitudinal Study

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this project is to maintain a database on the status of independent living programs (ILPs) nationally, and to identify trends in the development of ILPs, the emergence of issues encountered in the delivery of independent living services, and changes in the characteristics of consumers of these services.

Progress—Profiles of each program responding to a full-length survey have been published in the *ILRU Registry of ILPs*. In late 1988, a revised and updated survey instrument was mailed to over 400 programs listed in the *ILRU Directory of Independent Living Programs*. Information was solicited concerning populations served, services provided, characteristics of persons providing services, methods by which services are provided and programs administered, sources of funding, and relationships between programs and their communities. Responses from 189 programs were received and analyzed. A manuscript describing the evolution of independent living programs in America and comparing 1988 with 1986 results has been submitted for publication.

Results—A comparison of the 1986 and 1988 results has revealed some promising trends. Significant improvements have been made in both the volume and quality of service delivery; board and staff training; proportions of boards, executive directors, and staff with disabilities; and the size of federal grants. In 1988, more than three-fourths of the programs offered training to the board, and 94.7% offered training to the staff. By contrast, only 6% of the programs reported offering board training and 11% staff training in 1986. People with disabilities now occupy a majority of executive director, administrative, and staff positions, compared to filling less than half of these positions in 1986. In 1986, only 51% of programs receiving Title VII funds complied with National Council on

Disability (NCD) standards for the involvement of persons with disabilities in direction, management, and service delivery. Compliance had risen to 82.6% by 1988, and unlike 1986 findings, there was a significant relationship ($p < 0.05$) between compliance and both the receipt of funds and the amount of funding received. Complying programs offered significantly more services and served significantly more persons than did noncomplying programs. These findings have strong implications for federal policy and funding in the independent living area.

Additional analyses were done to determine the impact of program age, consumer control, and budget size on the operation of independent living programs. Results reflected the wide diversity of program characteristics. Older programs tended to have more diverse funding. Programs with higher levels of consumer control tended to have more staff with disabilities, engaged in more advocacy activities, and participated more in networks. Programs with larger budgets were more likely to offer residential housing services and were less active in advocacy and awareness activities.

Future Plans—The *Directory of Independent Living Programs* is updated and reissued approximately 5 times per year. Research staff will continue to update the *Directory* and respond to specific inquiries with individualized data runs and reports. Analysis will continue on the ILRU National Database on Independent Living Programs, with trends published as they emerge.

Recent Publications Resulting from This Research

Levels of Compliance with Federal Requirements in Independent Living Centers. Nosek MA, Jones SD, Zhu Y, J Rehabil 55(2):31-37, 1989.

Independent Living Programs: The Impact of Program Age, Consumer Control, and Budget on Program Operation. Nosek MA, Roth PL, Zhu Y, J Rehabil 56(4), 1990.

[265] The Definition of "Peer": Consumer Perspectives and Significance in the Delivery of Counseling Services

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This project is intended to assess the perceptions of disabled persons regarding the definition of peer and the provision of counseling services by peers. Peer counseling is essential to consumer involvement in independent living programs, as evidenced by the mandatory inclusion of peer counseling in all independent living programs receiving funding under Title VII of the 1978 Amendments.

Progress—The quasi-experimental design of this project focused on perceptions of counselor credibility. The research question asked which factors account for the greater variance in ratings of counselor credibility: disability status of the counselor, whether or not the counselor was professionally trained, or whether or not the content of the interaction was disability-related. Seventy-two subjects completed selected items from the Counselor Effectiveness Rating Scale, after viewing photos of four counselors, reading and hearing biosketches for each, and listening to tape recordings of two consumers describing a problem to a counselor.

Results—The data were analyzed using a double multivariate repeated measures analysis of variance within

subjects factors (Professionalism, Disability, and Vignette content, each with two levels) and five dependent variables (Experience, Expertness, Interest, Understanding, and Ability). Although the three-way interaction among Professionalism, Disability, and Vignette content was not significant, all three multivariate two-way interactions were statistically significant. An important finding of the study is that disability status of counselors significantly affects ratings of counselor credibility. For both professionals and nonprofessionals, disabled counselors received higher mean ratings than did nondisabled counselors on all five measures, although this difference was smaller for professionals. Also, for the disability content interaction, subjects rated disabled counselors more favorably than nondisabled counselors on all five measures.

Recent Publications Resulting from This Research

Perceived Counselor Credibility by Persons with Physical Disability: Influence of Counselor Disability Status, Professional Status, and the Counseling Content. Nosek MA, Fuhrer MJ, Hughes SO, Rehabil Psychol (in press).

[266] Independent Living in Rural Areas: A Longitudinal Study

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Under a 3-year grant from NIDRR, ILRU expanded independent living opportunities for disabled residents of rural areas. Five demonstration sites were established and given ongoing support until the project was completed in April 1986. The current Research and Training Center project is designed to examine the long-term effects of these interventions in terms of quality and quantity of ongoing activities and outcomes for the community.

Progress—The first component of this evaluation project involved an initial assessment of two demonstration sites when the ILRU rural demonstration grant was completed. This initial assessment enabled the collection of baseline data to be used for comparison in subsequent years. Follow-up assessments were completed after 18 and 36 months, from 1984 through 1988, in two sites using the Community Needs and Resource Survey as well as personal interviews with people with disabilities, religious

leaders, and media representatives. Results reflect different needs predominant in each community.

Results—Two of the five demonstration sites established independent living centers, while the other three sites pursued other options for service delivery. The in-depth studies of two sites yielded contrasting outcomes. The independent living project in Site I resulted in the establishment of a fully operational center for independent living (CIL). The Site II project had a positive impact on incorporating the independent living philosophy into the service delivery system and increasing the number of accessible public buildings and the number of citations for illegal parking in handicapped spaces, but did not lead to the development of a CIL. From 1984 to 1988, a substantial increase in accessibility in the following areas was realized in Site I: health care, housing, employment, attendant services, information and referral services,

transportation, and public buildings. Personal interviews substantiated data collected by the Community Needs and Resource Survey. Information gathered revealed the importance of several factors in successful establishment of CILs in rural communities: real and perceived needs of persons with disabilities in the community, availability and adequacy of existing resources to meet needs, and availability of people to provide leadership and continuing efforts.

Recent Publications Resulting from This Research

- Delivering Independent Living Services in Rural Communities: Options and Alternatives. Potter CG et al., Rural Spec Educ Q (in press).
- Independent Living Services for Children with Disabilities in Rural Areas. Smith QW et al., Rural Spec Educ Q (in press).
- The Personal Assistance Dilemma for People with Disabilities Living in Rural America. Nosek MA, Rural Spec Educ Q (in press).

[267] Instrumental Social Support as a Buffer of Psychological Stress for Persons with Physical Disabilities

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—A primary purpose of this investigation is to understand some of the principal determinants of psychological stress in people with physical disabilities. The research model underlying this project is based on the well-documented finding that social support can buffer the negative effects of stressors. According to Schaeffer, Coyne, and Lazarus, social support may take the form of instrumental support (e.g., direct assistance with tasks). For people in the general population, most studies have found that emotional or cognitive support is more important than instrumental support in buffering stress. People with severe physical disabilities, however, face distinctive stressors involving task demands of daily living (e.g., dressing, personal hygiene, preparing meals, shopping, and mobility throughout the community). Therefore, assistance with daily life activities comprises an important form of instrumental social support for people with severe physical disabilities. This study is designed to test the hypothesis that instrumental social support, specifically, personal assistance with activities of daily living, is a key factor in determining the degree to which physically disabled people experience stress and psychological

dysphoria. Also examined is whether the life satisfaction of disabled persons is related to severity of disability and satisfaction with social support provided by personal assistants.

Progress—Staff in eight centers for independent living in Federal Region VI recruited subjects for the study and distributed questionnaire packets. Upon receipt of completed surveys, the researchers interviewed subjects by telephone concerning their levels of social support. Approximately 81% of subjects returned surveys and participated in telephone interviews. A sample of 49 respondents used personal assistants. Data analysis is complete, and a manuscript presenting the results is in progress.

Results—Individuals with relatively severe physical disability and more unsatisfactory personal assistance were found to exhibit particularly high levels of perceived stress and psychological dysphoria. A moderately negative relationship was found between perceived satisfaction of personal assistance and extent of self-assessed stress and psychological dysphoria in persons with

physical disability ($p < 0.05$). The extent of self-assessed stress and dysphoria, however, had little or no relationship to severity of physical disability. These findings

suggest that satisfaction with personal assistance positively impacts life satisfaction, an effect that is relatively stable across disability levels.

[268] Development of an Instrument to Measure Adequacy of Personal Assistance Services

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This series of studies is designed to develop and test an instrument for assessing the adequacy of various systems for delivering personal assistance services to persons with diverse severe physical disabilities, their satisfaction with these services, and the effects of personal assistance on employability and health.

Progress—Summaries of more than 150 publications related to personal assistance were compiled and published in 1988. Since then, a literature-based list of personal assistance program components and characteristics relevant to adequacy has been generated and validated by expert review and field testing. During the process of developing adequacy criteria and indicators, it has been necessary to distinguish between assessment and adequacy from a consumer perspective versus a formal program review. Since methodologies for administrative evaluation of programs are abundant and consumer-focused adequacy criteria scarce, development

proceeded from a consumer perspective. It was also necessary to identify distinctions between adequacy and consumer satisfaction and incorporate satisfaction criteria into the instrument. After finalization of criteria and categorization of items by topic, operationalized indicators were developed. The resulting working draft of the instrument—the Personal Assistance Satisfaction Index—has been used in several studies to evaluate model personal assistance services and to assess the role of personal assistance in the health and employability of people with severe disabilities. Statistical analysis to determine the internal validity of indicators and factor analysis to test the validity of criteria categories have been performed. These results will be used to further refine the instrument.

Results—Factor analysis of the adequacy criteria revealed two prominent factors, quality/control and availability/cost. Item reduction analyses are currently underway.

[269] Arrangements for Receiving Personal Assistance Services

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This study is designed to identify the most common arrangements for receiving personal assistance services; to evaluate quality, control, availability, and cost in four different models of personal assistance programs; and to assess the satisfaction levels of persons with severe physical disabilities who obtain personal assistance through these program models. Relationships among living arrangement, who provides assistance, employment status, and productivity will be assessed.

Recommendations will be made for making formal personal assistance more acceptable, affordable, and available to persons who rely on family assistance (79% of people with disability-related functional limitations), but who could be more productive with additional hired assistance.

Progress/Methodology—The Baylor College of Medicine Research and Training Center on Spinal Cord Injury and

Independent Living Research Utilization (ILRU) have used a registry of 655 persons with spinal cord injury (SCI database) to assess relationships between living arrangement and provision of personal assistance by family, nonfamily, or a combination of both. This now comprises the control group for all subsequent studies of quality, control, availability, and cost of personal assistance services.

Productivity will be assessed by using SCI data that correspond to five components of DeJong's Productivity Scale—work status, educational status, activities outside the home, activities inside the home, and homemaking activities. The resulting productivity score will be analyzed with living arrangement and who provides assistance in a two-way analysis of variance (ANOVA).

To assess relationships between satisfaction with personal assistance and age, duration of disability, living arrangement, income source, productivity, marital status, educational attainment, number of hours of assistance used, and who provides assistance, the above results will be combined with data from telephone interviews of 75 subjects from the SCI database who use more than one hour of assistance daily. These subjects have been selected using stratified random sampling procedures and are currently being interviewed. Twenty-five of the sample use family assistance only, 25 nonfamily only, and 25 a combination. Interviewers are trained consultants from the Houston community who use personal assistance themselves. The interview content consists of demographic information and the Personal Assistance Satisfaction Index.

Relationships between control and satisfaction are being evaluated in four different models of personal assistance delivery: 1) state provision; 2) independent living center provision; 3) home health care agency provision; and, 4) consumer co-op provision. The Personal Assistance Satisfaction Index was mailed to 87 consumers who obtain personal assistance through these programs, and data were analyzed using one-way ANOVA, and the Tukey multiple comparison test.

Preliminary Results—The preliminary study of 655 persons with spinal cord injuries revealed that of the 286 who used personal assistance, 77% lived with relatives. Of those, family provided assistance to 61%, nonfamily assisted 17%, and a combination of family and nonfamily assisted 22%. Of the 10% living with nonfamily, most (70%) received assistance from nonfamily, and of the 13% living alone, nearly everyone received assistance only from nonfamily. Disregarding living arrangement, 50% were assisted by family only, 31% were assisted only by nonfamily, and a combination assisted 19%. The reasons for the unexpectedly higher rate of paid assistance usage will be explored in subsequent studies comparing differences between persons with spinal cord injury and those with other disabilities. One possible explanation is that persons with spinal cord injury may be more likely than persons with other types of disabilities to have access to private sources of funds, such as insurance settlements, and to have had formal rehabilitation that included training in managing assistance needs.

Preliminary results from the survey of use of four personal assistance models indicate that satisfaction levels were significantly higher ($p < 0.05$) for the 25 consumers who obtained services through a progressive home health care agency. This model enabled the greatest flexibility in consumer control: consumers in this highly satisfied group had the option of deciding the extent of the agency's involvement in arranging personal assistance services. Satisfaction levels with the home health care agency were significantly higher than satisfaction with the state provider and the consumer co-op models, but only slightly higher (nonsignificant) than the independent living center.

Recent Publications Resulting from This Research

Personal Assistance Services: A Review of Literature and Analysis of Policy Implications. Nosek MA, J Disabil Policy Stud (in press).

[270] Effect of Personal Assistance Services on the Long-Term Health of a Rehabilitation Hospital Population: Perceptions of Rehabilitation Professionals

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This study is designed to test the hypothesis that personal assistance with activities of daily living

significantly affects the ability of persons with severe physical disabilities to maintain good physical health.

Five research topics will be specifically addressed: 1) in the rehabilitation hospital population, the frequency of health problems and preventable complications of disability that can be attributed largely to inadequate personal assistance services will be determined; 2) any differences will be observed in the health status of persons who use personal assistance from family only, paid employees only, or a combination of family and paid employees; 3) services that rehabilitation facilities offer to assist patients in obtaining and managing personal assistance will be identified and evaluated; 4) common complaints will be described about problems in obtaining and managing personal assistance that rehabilitation professionals often hear from persons with disabilities; and, 5) recommendations from rehabilitation professionals will be solicited about what changes are needed in personal assistance services and policies.

Progress/Methodology—A sample of 100 subjects have been selected from the membership of the American

Congress on Rehabilitation Medicine (ACRM) and are currently being interviewed by phone. Interviewees consist of 2 physicians, 2 nurses, 2 social workers, 2 physical therapists, and 2 occupational therapists from each of 10 medical rehabilitation centers. Data will be analyzed using techniques of qualitative investigation. Comments will be categorized and coded for frequency analysis. Simple bivariate procedures may be used to determine relationships among certain types of responses and characteristics of the subjects.

Preliminary Results—Preliminary results from a population with spinal cord injury indicate that a significant portion of persons who use personal assistance services have an abnormally high rate of hospitalization and use of emergency medical services. The portion of variance accounted for by the adequacy of personal assistance services received is yet to be determined.

[271] Occupational Stress Among Executive Directors of Centers for Independent Living

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Purpose—This first phase of this study is designed to investigate sources of occupational stress, techniques and resources for coping, and strain that results when work demands exceed the coping resources of executive directors of independent living centers (ILCs). In the second phase, these aspects of occupational stress will be investigated in the middle management staff of state rehabilitation agencies and compared with the results from executive directors of ILCs.

Progress—The *Occupational Stress Inventory* (OSI) developed by Osipow and Spokane—consisting of Occupational Roles, Personal Strain, and Personal Resources questionnaires—was mailed to the executive directors of 316 independent living programs listed in the *Directory of Independent Living Centers and Programs* maintained by the ILRU Research and Training Center on Independent Living in Houston, TX. A total of 141 usable questionnaires were returned for a response rate of 45%. Data analysis was completed and a dissertation of the results

was presented in January 1990 at Southern Illinois University at Carbondale.

By using a random sampling procedure stratified according to scores on the OSI, 25 of these respondents were chosen and interviewed by telephone to obtain more specific information about occupational stress. Data are currently undergoing analysis.

For the second phase, the OSI was mailed to approximately 400 administrators of four state rehabilitation agencies.

Results—Role overload was strongly related to strain, despite the availability of many resources. Role insufficiency, however, was not strongly related to strain. Executive directors were able to decrease strain through regular participation in recreation and the use of logic and rational problem-solving strategies when faced with specific stressors. The level of strain that executive directors experienced was similar to that experienced by other technical, professional, and managerial workers.

Future Plans/Implications—Possible reasons will be explored for role overload in executive directors and what

specific problem-solving techniques they use to reduce specific stressors.

[272] New Models for the Provision of Personal Assistance Services

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Purpose—Various social forces, including the growth of the independent living movement, increasing numbers of older people, increasing numbers of working women, advances in lifesaving technology, and deinstitutionalization have combined to put the issue of home/community-delivered personal assistance services (PAS) on the U.S. public policy agenda. The inadequacy and inequity of the system(s) which provide these PAS through public financing recently have begun to be defined and documented. With the increased interest in improving services, policy-makers have debated the size of the need and demand for publicly funded PAS, the potential cost, and best methods for meeting this demand.

The current research objectives are to: 1) identify existing research on PAS, emphasizing data on need, use, cost, and evaluation of services; 2) analyze current systems of providing PAS, including: sources of payment; recruitment, training, and management of assistants; types and levels of service provided; costs of services; program growth, cost of control methods and quality assurance methods; and degree of consumer control; 3) develop strategies for implementing more effective models of PAS, including those aspects which will assure more comprehensive and beneficial services to individuals and greater consumer satisfaction; and, 4) analyze the effect of using PAS on employment, earnings, medical care utilization, and the receipt of cash benefits.

Methodology—The research is being conducted by two centers. The World Institute on Disability (WID) built on its 1985 survey of the universe of PAS programs in the U.S. by conducting a follow-up mail survey of previously interviewed programs as well as new ones. In addition, WID developed case studies on 16 programs through telephone interviews and review of program management documents. These programs are the largest ones funded by the seven different funding sources at three levels of consumer control. The results of these two surveys are now being analyzed to develop models for more effective PAS delivery under the seven current PAS funding schemes.

The Rutgers Bureau of Economic Research has analyzed the Survey of Income and Program Participation, and is conducting a personal interview survey of a national sample of people with spinal cord injuries, to shed light on the users of PAS and the impact that the need for PAS has on their lives. They also examined the Management Information Systems (MIS) of the 16 case study programs which had such systems, and are developing a model MIS for PAS programs.

Preliminary Results—Results of the research are being examined. They will include the following reports from: 1) Rutgers—Model MIS, Estimating the Need for PAS, The Predictors of Need and Demand for PAS; and, 2) WID—Effect of Government Fundings Source on Personal Assistance Programs: Summaries of 1985 and 1989 Surveys, Changes in PAS Programs Between 1984 and 1988; Case Studies on 16 Representative PAS Programs; and, strategies for implementing more effective models of PAS, including those aspects which will assure more comprehensive and beneficial services to individuals and provide greater consumer satisfaction.

Future Plans/Implications—The major outcome of this research will be to provide policymakers and planners on the national and state levels with the quality of information they need to develop a comprehensive and effective PAS system. This research will allow policymakers to project the costs of a more adequate and equitable PAS system based on new cost, demand, and utilization figures. We should gain a better understanding of how funding source mandates, along with state creativity, have shaped the various ways in which services are delivered. As a result, we will be able to better describe mechanisms that policymakers can use to develop systems that better meet the PAS needs of people of all ages with disabilities. Finally, we hope to gain a clearer picture of how PAS consumers pay (or don't pay) assistants, who the assistants are, and the degree of need for public funding of PAS.

Under the auspices of the new Research and Training Center in Independent Living Policy at WID, we will be building upon the WID research to estimate the cost of a national program of PAS for all who need it, based on projections from actual cost of existing programs and the predictions of type of service and hours needed from the National Spinal Cord Injury Survey.

Recent Publications Resulting from This Research

The Need for Personal Assistance. Rutgers University—Bureau of Economic Research and the World Institute on Disability. Berkeley: World Institute on Disability, 1989.

[273] High School Prevocational Intervention Study

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—The vocational difficulties of persons with epilepsy include elevated rates of unemployment and historically low rates of movement into competitive employment through state rehabilitation agencies. Much of the current literature suggests that job development strategies, and not traditional skills-training programs, are most effective in assisting brain-impaired persons to secure competitive jobs. Initiating vocational habilitation work at the high school level is believed to be desirable because: 1) individuals with early onset of epilepsy are more likely to exhibit deficits in neuropsychological, intellectual, and social status than are individuals with postadolescent onset; 2) chronic unemployment as a lifestyle may occur early in this population; and, 3) there may be locus of control, or “learned helplessness” factors present which are more amenable to early intervention.

A prevocational intervention is proposed which is designed to assist epilepsy-impaired high school seniors to enter competitive employment at an early time. It is

hypothesized that the treatment group, relative to placebo and no-treatment controls, will demonstrate: 1) a higher rate of entry into competitive employment; and, 2) a reduced rate of dependence on public subsidy.

Methodology—The treatment is presented in a group format, designed after successful group formats currently used in this center for adult outpatients with epilepsy. Pilot work is presented which suggests the feasibility of using neuropsychological testing results obtained from high school age epileptics as an index of later vocational status. Pilot work also shows an early reliance on public subsidy for epileptics who were subjects in a post-high school vocational status study. Hypothesis testing will proceed by means of *t*-tests, rank correlation coefficients, and distribution-free analyses of variance, and will be adjusted for multiple comparisons. Multiple rank regression methods will be used as an aid in identifying types of individuals who may be expected to benefit from extended or specialized services.

[274] Rehabilitation Engineering Center

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Sponsor: National Science Foundation; National Institute on Disability and Rehabilitation Research; Texas Department of Mental Health and Mental Retardation

Purpose—This program provides rehabilitation engineering consultation at state Mental Health and Mental Retardation facilities, schools, and other sites utilizing bioengineering faculty, bioengineering students, and special education students. The program provides for design and modification projects which benefit

individual clients or are used within the facility for client treatment or education. Technology workshops are also provided. In addition to direct services, the program is also intended to enhance the rehabilitation technology capabilities of present and future practitioners.

Progress—This is an ongoing program. Initial efforts consist of meetings at each facility to acquaint the staff with the program and the types of projects which would be consistent with available resources. This is followed by frequent meetings to identify and implement projects. A wide array of electronic and mechanical devices have been designed and delivered under this program. In addition, design and electronics workshops have been conducted to enhance the technical skills of on-site personnel.

Results—The direct result of this work is the delivery of new or modified adaptive equipment directly into the rehabilitation and special education settings. Communication devices for nonverbal and motor-limited clients have been developed which allow for simple selection from a limited menu using a variety of input devices. Additional projects included several types of interfaces between clients and environmental devices, and prevocational training devices which provide a reward feedback for completed tasks. Sheltered workshop task design problems were addressed to improve workers' efficiency, and to bring new contracts to the workshop. Music therapy for the child with disabilities has been enhanced through the design of a joystick-controlled musical keyboard. Additional projects in the school setting included aids for teaching mathematics and writing, modifications of self-feeding aids, and the provision of portable equipment for the district's occupational therapist. A micturition alarm was provided for adult residential clients to enhance attendant care. A large-switch television remote control was also developed for a residential setting. Several postural feedback systems were provided, including one using a zero-force shadow switch.

A variety of innovative physical therapy and occupational therapy equipment, including an adjustable height platform and ramp for wheelchair training, and a thumb-extension system with capacity to operate external

devices has also been designed. These devices provide extensive visual and auditory feedback to encourage the young user. Voice/sound-controlled systems for speech therapy have also been developed to enhance vocalization training in children.

Future Plans/Implications—Experience with this program has demonstrated that there is an ongoing need for engineering design input for a variety of client problems at these facilities. The service model has advantages in that continuous engineering services could not be effectively utilized by these facilities at this time. Moreover, this program includes an array of expertise and experience and the resources of the University for fabricating projects.

Future plans include expanding the program to cover more state and school facilities. Technology training for therapists and teachers will also be further developed. For the engineering student, this program provides an opportunity to solve real-world problems, obtain exposure to rehabilitation engineering, and gain an understanding of individuals with handicaps and their needs. The special education student receives experience in applied technology and the model of using engineering students as a low cost design resource.

Recent Publications Resulting from This Research

- Engineering Student Design Projects in Physical, Occupational and Speech Therapy. Hyman WA, Miller GE, in Proceedings of the 12th Annual RESNA Conference, New Orleans, 375-376, 1989.
- Texas A&M Rehabilitation Engineering Projects. Hyman WA, Miller GE, in Engineering Senior Design Projects to Aid the Disabled. Washington, DC: National Science Foundation, 1989.
- Undergraduate Bioengineering Student Design Projects Applied to Real World Problems for the Handicapped. Miller GE, Hyman WA, Int J Appl Eng Educ 5(4):451-456, 1989.
- Applications of Force Sensitive Resistors. Hyman WA, Miller GE, in Proceedings of the 13th Annual RESNA Conference, 201-202, Washington, DC, 1990.

[275] A Computerized Information Network Supporting the Choice of Technical Aids

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Sponsor: *The Region of Lombardy; The Region of Campania; The National Research Council*

Purpose—The goal of this project was to set up a computerized data bank of technical aids and a Technical Aids Counseling Centers network.

Methodology—The first version of the data bank was developed by SIVA on a mainframe (DEC VAX 11/750) and became operational in 1982. Remote access was

available through a modem and telephone line. In 1988, demand for accessing the system increased rapidly among the local health authorities, regional governments, and associations of disabled persons. The data bank was completely rewritten for implementation onto personal computers. The current version requires a MS/DOS-compatible PC with 640K bytes RAM and at least 15M bytes hard disk. Files are organized using DBIII+ format and software has been written by SIVA in Clipper language. The software interface is user-friendly and specially developed for rehabilitation professionals. Extensive user-friendly evaluation has been carried out with over 100 rehabilitation professionals throughout Italy. Distribution of the data bank outside SIVA was organized through quarterly mailing of floppy disks. Every update is a new version of the whole package (data and software) which supersedes the old one. By using data-compression utilities and specific software developed by SIVA, it is possible to store the whole package onto a single 1.44 floppy disk and rebuild the operational version on site. The data bank is always accompanied by a specific training program for the professionals at the local centers

who are concerned with a global approach to counseling on the choice of technical aids.

Results—The data bank currently contains information (continuously updated by a team of experts) on approximately 4,000 technical aids, 5,000 organizations (commercial and noncommercial), legislation concerning the provision of technical aids, selected literature, and criteria for choosing technical aids. A record of the counseling services given to the clients can be kept through a standardized form that is also used as a basis for statistics and follow-up. Fifty-two rehabilitation centers throughout Italy are now accessing the system.

Future Plans—An extension of the information network is foreseen in order to provide qualified information to all disabled Italian persons through the rehabilitation centers.

Recent Publications Resulting from This Research

The Italian Computerised System Supporting a Network of Technical Aids Counselling Centres. Andrich R, in Proceedings of ECART 90, Maastricht, 1990.

[276] Creation of a Regional Network of Technical Aids Information Centers in Lombardy, Italy

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Sponsor: *The Region of Lombardy*

Purpose—The purpose of this project was to create a network of technical aids information centers throughout the regional territory, with SIVA taking the lead at two levels: information management (i.e., collection, processing, distribution), and specialized counseling.

Methodology—There are 80 local health units (USSL) responsible for the health care and social services in Lombardy. Fourteen USSLs were selected to represent the region for the experimental period between 1988 and 1990. In order to create a multidisciplinary team for each information center, the USSLs were asked to identify three categories of professionals suitable for this purpose: a person responsible for the project (frequently chosen was a medical doctor specializing in rehabilitation and responsible for prescribing technical aids), at least two rehabilitation therapists already part of the rehabilitation staff and willing to be directly involved with counseling

in the information center, and an administrative officer charged with prescription control.

Courses were organized to prepare the professionals for their new tasks: 1) technical aids (1 week); 2) information retrieval and documentation handling, including practical experience of the SIVA computerized data bank (3 days); and, 3) counseling (1 week). All information centers were planned to be accessible for disabled persons, and designed to facilitate communication among the staff. The data bank was implemented onto a PC Olivetti M240 and distributed to all 14 centers. During the project, the data bank was updated quarterly.

Results—The Technical Aids Information Centers are now working regularly in 11 of the 14 USSLs chosen for this project. The centers are open to the public 2 or 3 days a week (for a total of at least 10 hours a week).

Future Plans—The Region of Lombardy is considering the possibility of extending the experiment to the other

USSRs to include the activities of the local information centers into the general routine of the rehabilitation units.

[277] Independent Living at Home for Severely Disabled Persons: An Experimental Project

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Sponsor: *The Region of Lombardy, National Research Council*

Purpose—The purpose of this study is to verify to what extent severely disabled persons can achieve or maintain a degree of personal autonomy when performing the activities of daily living with the support of technical aids.

Methodology—The project sample consisted of 12 quadriplegics with a wide range of disabilities, but with no severe cognitive limitations. The pathologies concerned were cerebral palsy, multiple sclerosis, and trauma.

Selection of the sample group for this 3-year project was based on various parameters—ability to modify living quarters, implementation of technical aids, and the execution of the necessary modifications.

Of the 72 families interviewed, 12 filled the requirements for participation in the study. The following were distributed to the clients and their families: 76 communication aids (including hardware, software, switches, etc.); 42 mobility aids (including manual and powered

wheelchairs); 18 pieces of stair-climbing equipment; 12 hoists; 12 beds; 10 bathroom modifications; and 7 anti-decubitus aids. The majority (more than 80%) of these technical aids needed specific personalization.

Results—Twelve families were involved in the project and can now be considered more independent in their daily lives. Technical aids and proper training dramatically reduced the need for personal assistance for the most frequently performed tasks of daily living.

Future Plans—An extension of this project is deemed necessary in order to validate the findings.

Recent Publications Resulting from This Research

Experimentation for Counseling, Personalization, and Teaching
How to Use Aids and Technical Devices for a Personal and/or
Housing Autonomy for Severe Quadriplegic People. Ferrario M,
in Proceedings of ECART 90, Maastricht, 1990.

[278] SEDL/Regional Rehabilitation Exchange

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Sponsor: *National Institute on Disability and Rehabilitation Research; Southwest Educational Development Laboratory*

Purpose—The Southwest Educational Development Laboratory/Regional Rehabilitation Exchange (SEDL/RRX) identifies, validates, and disseminates effective rehabilitation practices focusing on critical needs areas in Federal Region VI: Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.

The goals of the Regional Rehabilitation Exchange are twofold. The first goal is to promote the use of validated exemplary programs, products, and practices resulting from rehabilitation research, training, and service delivery in the areas of Independent Living Services, Job Placement Services, Supported Employment Services,

and Transitional Services. Using a detailed, uniform evaluation procedure that includes peer review, the RRX validates rehabilitation and independent living programs that are especially effective and recognizes them formally as exemplars. These exemplary program models generally demonstrate a high success rate, surpass established performance standards, show significant and stable results, are cost-effective, and include adaptable or transportable components. Six newly identified exemplary programs in 1989 and ten in 1990 were identified and validated throughout the four core areas to join previously identified programs as technical assistance resources.

The second goal is to provide technical assistance for program improvement and/or new program initiation purposes. In some instances, the RRX can broker and provide in-depth technical assistance to agencies or organizations. This is done by matching the technical assistance needs of the organization/agency/school with exemplary program components and service providers who have demonstrated expertise in those areas: RRX funding will provide the consultation fee and travel expenses of the consultant. Evaluations of technical assistance provided to organizations take place several times over the year following the activity.

Results—Greater results have been shown from the recipients receiving the technical assistance than the exemplary programs, due to the fact that the recipients did not have to develop a proven model through trial and error, thereby saving staff time and resources.

Results of this past year have included formal agreements with state agencies in each of the five states to

provide for the cooperation of the various state agencies and the RRX in the planning and implementation of services in the core areas listed above in order to obtain/maintain supported/transitional employment for individuals with severe disabilities within the state. Individual organizational agreements also took place for the purpose of program initiation or enhancement that lead to greater programmatic outcomes. Several special focus workshops also took place in the areas of "Successful Job Placement Services for Persons with Traumatic Head Injury," and "Exemplary School-to-Work Transition Programs."

Future Plans—The RRX is beginning its third year of a three-year NIDRR grant. Project goals for the third year are to continue to identify exemplary programs in RSA Region VI, as well as to provide technical assistance to service providers for people with disabilities in the areas of Independent Living Services, Job Placement Services, Supported Employment Services, and Transitional Services.

[279] Effect of Personal Assistance Services on Productivity and Daily Living Among Japanese with Severe Physical Disabilities

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Sponsor: *World Rehabilitation Fund*

Purpose—The purpose of this study was to pilot-test a methodology for assessing arrangements through which persons with disabilities obtain personal assistance to compensate for their functional limitations, levels of satisfaction with these services, and the effect that personal assistance services have on their productivity and daily living.

Progress—Thirty subjects were recruited from the Tokyo and Kansai areas with the assistance of the Human Care Association—an independent living center in Tokyo—and organizers of the Ninth Annual Conference of Wheelchair Users, held September 1989, in Hyogo, Japan. Persons who were active in disability-related consumer organizations such as independent living centers or advocacy organizations were recruited the most intensively. Each individual completed a written questionnaire consisting of demographic data: the Personal Assistance Satisfaction Index (PASI), and the DeJong Productivity Scale. Of this sample, 15 were also interviewed in person.

Results—The most common disability represented was cerebral palsy, followed by quadriplegia from spinal cord injury, then muscular dystrophy. Of the majority who lived with family (73%), only family provided assistance in 40%, only nonfamily did in 20%, and a combination assisted in 12%. The second most common arrangement was living alone (27%), in which nonfamily members, usually paid workers, provided assistance (24%). No one lived with nonfamily. The average amount of personal assistance used was 11 to 20 hours per week. Regarding payment for services, 44% received assistance free, 16% used their own funds, 12% used government-paid assistance only, 12% used a combination of free and government-paid assistance, and 16% used their own funds combined with free assistance. More than three-quarters of the subjects (78%) stated that they were dissatisfied with both the availability and the cost of personal assistance. There was no significant difference between the satisfaction scores of residents of Tokyo, where considerable city funding is available for personal

assistance services, and those from other parts of Japan, where funding is scarce. Those who lived alone but used nonfamily assistants had the highest level of satisfaction, while those who lived with family but had nonfamily assistants had the highest level of productivity. Individuals who were among the most satisfied were more likely to be married and to have nonfamily, paid assistants. Individuals who were among the most productive also tended to be married, older, and less educated.

Anecdotal data indicated a strong desire for more control over arranging personal assistance, greater availability of persons to serve as assistants, and more funds to pay them. Of the 15 subjects interviewed in person, 11 said they preferred family or hired persons as assistants. Those favoring family felt freer asking for the assistance needed, and the quality of assistance was better. Those who preferred hired personal assistants cited control over the selection of the assistant and the scheduling of assistance. Subjects who received assistance from the Home Helper system unanimously expressed dissatisfaction with their inability to choose the assistant and the patronizing attitude of the assistant. Eight subjects commented that they lacked enough personal assistance to achieve the level of productivity they desired. Reluctant to ask for the extent of assistance actually needed from family, many felt that they must sacrifice their productive aspirations to minimize the burden on their family.

Only a small portion of Japanese citizens with disabilities are competitively employed, which reflects not only a lack of appropriate assistance services, but also their exclusion from the mainstream educational system, as well as the negative attitudes of employers toward people with disabilities. Separate educational facilities fail to equip them with the social and educational skills necessary to compete in the real working world. In addition, architectural and transportation barriers limit their mobility in the environment. Consequently, the primary activities reported were volunteer work or participation in sheltered workshops.

Implications—The results of this study strongly suggest the need for national policies on personal assistance services in both Japan and the United States, as well as a commitment to establish national programs that offer broad personal assistance services at a reasonable cost and with a range of options for consumer control of the services. Only then can persons with physical disabilities realize their full potential for productivity in the community.

Recent Publications Resulting from This Research

Personal Assistance Services in Japan: Effect on Productivity and Daily Living Among Japanese with Severe Physical Disabilities. Nosek MA. New York: World Rehabilitation Fund, Inc., 1990.

[280] West German Building Standards to be Transferred as a New General Barrier-Free Building Code

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Sponsor: *None listed*

Purpose—New building standards were needed to establish barrier-free environments for disabled and elderly persons.

Progress—The West German building code DIN 18025 Part 2 (applicable in both parts of Germany) is the most advanced building standard for a general concept of a barrier-free environment and is, with great political support, on its way into legislation as an adaptation of general building codes.

It is an example of a joint European effort and is a concept to solve housing requirement problems of the disabled and elderly in environmental and urban developments.

This new set of regulations decreases the need for special housing and concentrates on integration by designing major multiples for a given and future situation of population mixture in age and disability.

Results—During the 2-year development of the new standards, a comparison was conducted to evaluate the differences in codes and standards of other European countries. It was concluded that a joint European concept, integrating adaptable housing features, is quite feasible.

A selection of various planning concepts applying the new codes (which define functional spacing with each object of use, instead of defining room sizes), is available

upon request for various selected home sizes and for single problem areas (e.g., bathrooms or kitchens). There is a charge for postage and handling.

Future Plans—Several experimental building projects have been initiated with the new concept, in order to have a comparable base of building cost between the traditional and the new type of barrier-free construction, including

vertical access to all building levels. A report and commentary containing these research results will be published with an addendum concerning all buildings accessible to the public, applying the same basic concepts, including that of barrier-free work- and job-sites for all.

The various reports and detailed publications will be available in Spring of 1991.

[281] Development of a Dynamic Interactional Rehabilitation Data System

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Sponsor: *None listed*

Purpose—The dual purpose of this project is to develop: 1) a factual international technology transfer system (interconnected within a service center network), offering access to an interactional data system for all rehabilitation research and development supplying information for local counseling; and, 2) a basic library for a first full university master study in rehabilitation engineering, to be launched in Aachen, Germany.

Progress/Methodology—We have completed development of software for a rehabilitation databank system which links data to the specific problem area, in direct relation to a given anatomic or disability situation, integrated with an additional link to a given area of application or use, enabling specification on research needs following feedback of performance information.

These links and interconnections (a capacity of 40 interconnections in depth and endless in length), enable direct comparative reference to a given matrix of anthropometric or ergonomic values. Any item or additional interconnection or link can be added during data entering without further programming. The basics of the data collection software offer extensions into macro structures for integrated links to other sources of information. There is a built-in provision for multiple addresses, and space for additional internal comments on each set of information. If the comments contain appropriate key words or

graphics (the system will eventually combine with a CAD surface and software), it will enable architectural and barrier-free counseling on all types of housing and environmental developments.

Future Plans—The software will provide additional integrated possibilities to include drawings, graphics, or scan-in photos for each set of data, and is designed to run on a 386 AT with at least 2 MB-RAM. It can communicate with central computer systems, and network with any type of data transfer possible with any type of data communication system. This system was developed especially for rehabilitation, and will provide all of the requirements for regular data collection (including filing and use of do-it-yourself solutions), for scientific research data, and medical or therapeutic information (e.g., architectural planning details). The system is in use at the Institute T.L.P.e.V. and will, after final development (scheduled for the summer of 1991), be offering services on three levels for: 1) individual disabled persons; 2) experts, therapeutic professionals, etc.; and, 3) scientific research.

We plan to open up the system to international cooperation and joint ventures and to interconnect with projects (e.g., research methods and application possibilities of traditional medicine and therapy from the People's Republic of China) to improve western rehabilitation therapy.

[282] Research of Therapy and Traditional Medicine Application in Rehabilitation in the People's Republic of China

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Sponsor: *None listed*

Purpose—Four years of preparation and investigation of the procedures and possibilities of rehabilitation in the People's Republic of China have clearly indicated the need to make the knowledge and procedures of a combination of Chinese traditional medicine with Western medicine (which mainly serves as ambulatory therapy), available to Western rehabilitation centers.

Progress—An agreement of cooperation has been signed between the Institute T.L.P.e.V. and seven of the leading Shanghai universities and research centers for rehabilitation and traditional medical application and adaptive Chinese technology. Preparations are being made for installation of the first information, training, and treatment center in one of the European Community countries, which will be staffed with rotating Chinese specialists from various fields.

Chinese rehabilitation techniques are not directly comparable to the Western concept, but the combined application of Western and traditional methods in China offers a totally new and fascinating chance for a major improvement of Western rehabilitation. We shall inves-

tigate to what extent methods are transferable (including knowledge and application of traditional herbal medication from China), during an exchange of specialists from both sides. Three of the leading German rehabilitation centers are preparing to coordinate and take part in this 5-year project, for which a request for German federal research funding is being submitted.

Chinese researchers have developed some low-cost memory-shape alloys for orthopaedic applications and low-cost endoprosthetic implants and artificial joints, and have also combined functional electrical stimulation with traditional acupuncture. This technique uses lasers plus acupuncture needles, instead of wholly relying upon needles. These methods are some of the technology presently being investigated in detail for development in China.

Future Plans—We intend to open this project for participation by scientific or rehabilitation centers of other countries, and to organize a joint venture in research evaluation which will consider the interdisciplinary individual interests of such countries.

[283] Development of Methods for Egress of the Disabled and Elderly from Private or Public Buildings

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Sponsor: *None listed*

Purpose—This is both a project report and an urgent call for joint action on a matter of mutual concern for all countries, namely, the question of emergency egress for disabled and elderly from buildings. The need to provide not only "access for all," but to solve the problem of egress for disabled and elderly people from any type of building in case of emergency has been neglected.

Sufficient provision of egress has been given far less attention than has equal access.

Practical solutions or detailed information for the rescue of disabled or elderly people from burning buildings are not available. This applies whether those buildings are private homes, apartment buildings, or public-accessible buildings of any kind. Most building

codes make no special provisions for the disabled or elderly, and all safety codes have been formulated based on able-bodied persons.

Progress—A preliminary investigation of building codes and standards of 32 countries has shown that no special consideration is given to handling the evacuation of disabled or elderly people in case of fire or other emergencies, except for advice for special attendant care. The Institute T.L.P.e.V. has joined forces with the University of Ulster to launch a research and development project

to find solutions and to develop basic requirements to be included in all building codes and technical safety standards.

Implications—This is an international matter of mutual concern and responsibility for all countries. It is presented as an offer for a joint venture on research. Through an understanding of technology transfer, we hope to exchange information, and combine international knowledge and abilities to solve this problem of mutual interest and importance.

VIII. Muscles, Ligaments, and Tendons

For additional information on topics related to this category see the following Progress Reports: [122], [344], [567].

A. Muscles

[284] Noninvasive Electromyography

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Sponsor: VA Rehabilitation Research and Development Service (Project #B496-RA)

Purpose—Clinical electromyographic (EMG) signals are currently recorded using intramuscular needle electrodes. Noninvasive surface electrodes would be less painful and more easily accepted by many patients, especially children. However, since EMG signals are attenuated and distorted by the subcutaneous tissues and skin, surface EMG recordings have been considered unsuitable for electrodiagnosis. Recently, new electrodes have been developed to overcome some of this distortion. They consist of an array of small surface contacts whose outputs are combined via a spatial filter. We are interested in optimizing the design of these electrode arrays and in developing methods to analyze the signals they record.

Progress/Methodology—In order to investigate the influence of the size and shape of the surface electrode on the electrical properties of the recorded signal, we measured the electrical impedance of electrodes ranging in size from 0.02 to 0.125 inches in diameter and having

cylindrical, hemispherical, and conical shapes. Each electrode was pressed against the skin over the abductor pollicis brevis or the brachial biceps with a constant force (50 g). The skin had been rubbed with an alcohol wipe. The impedance between the test electrode and a large ground electrode on the forearm was measured as a function of frequency from 10 to 1,000 Hz.

Results—Impedance decreased with frequency for all electrodes. As a function of size, impedance was less for the larger electrodes, because of increased contact area, and for the smaller electrodes, because of increased contact pressure. Conical electrodes had lower impedances than cylindrical and hemispherical ones at low frequencies (1 versus 10 megohms at 10 Hz, 0.125 in diameter), but roughly the same impedances at high frequencies (0.1 megohms at 1,000 Hz). We conclude that small electrodes with tips sharp enough to indent but not pierce the skin have sufficiently low impedances to be practical for surface recording.

[285] Muscle Fiber Recruitment During Submaximal Electrical Stimulation

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Sponsor: VA Rehabilitation Research and Development Service (Project #B591-RA2)

Purpose—The purpose of this project was to determine the distribution of muscle fibers activated using transcutaneous electrical muscle stimulation (EMS).

Results—This study was based on the observation that, in spite of the relatively low torque levels achieved with 50 Hz EMS (average torque = 15.2% \pm 16.8% of maximum

voluntary contraction levels; mean \pm standard deviation, $n=40$ subjects), all subjects complained of muscle soreness which is not associated with 15% voluntary contractions. We hypothesized that either a superficial "shell" of fibers was activated, or perhaps a certain fiber type was preferentially activated. In a rabbit neuromuscular model, we repetitively activated the tibialis anterior (TA) to (initially) about 20% maximum tension for approximately one hour. After about one hour, force had dropped to an average of 1.3% of maximum. Muscles were then rapidly frozen and stained for fiber type, and active fibers identified using the glycogen depletion method. The distribution of fiber types present in the sample area was: $45 \pm 4\%$ FG, $42 \pm 5\%$ FOG, and $13 \pm 4\%$ SO fibers. However, the distribution of fiber

types depleted (i.e., activated) in the sample area was: $73 \pm 6\%$ FG, $18 \pm 5\%$ FOG, and $9 \pm 6\%$ SO fibers. In all cases, there was a significant difference between activated fibers and fibers present.

Implications—These data suggest that neural stimulation via a cuff electrode can preferentially activate a specific fiber type.

Recent Publications Resulting from This Research

Human Quadriceps Muscle Fatigue at Three Frequencies and Two Duty Cycles Through the Utilization of Functional Electrical Stimulation. Robison MJ, Lieber RL, in Proceedings of Cumberland College 7th Conference on Motor Disturbances, 7:45, 1989.

[286] Biochemical and Myoelectric Events During Fatigue

C.J. DeLuca; L. Brody; M. Pollack; S.H. Roy; B. Celli

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 1); Boston University Medical Center

Purpose—This project is designed to gain more detailed understanding of how biochemical changes associated with fatigue influence the behavior of the median frequency and conduction velocity estimates of the electromyographic (EMG) signal. Neuromuscular strip preparations from the hamster diaphragm were studied *in vitro*. A specialized array of surface EMG electrodes was designed and developed for monitoring EMG signal spectral parameters and conduction velocity from electrically elicited contractions. The diaphragm muscle strip was instrumented to record its contractile tension. The experimental setup provided a unique opportunity to directly control the biochemical conditions of the muscle environment and record this effect on the electrophysiologic and contractile state of the muscle.

Progress—We conducted two studies this year. One series of investigations was recently completed to establish a causal relationship between muscle pH and the EMG signal. Muscle pH (or $[H^+]$) is believed to play a key role in muscle fatigue and the concurrent changes in the EMG signal. A series of sustained contractions were electrically elicited at varying bath pHs in a total of eight preparations. The results indicate that the initial median frequency and initial conduction velocity changed by equal percentages as a function of bath pH. This finding implies that the

change in conduction velocity causes a compression (or expansion) of the M-wave rather than a change in its fundamental shape. In contrast, during sustained muscle contractions, median frequency changed by a greater percentage than conduction velocity. This observation implies that, in addition to the changes due to conduction velocity and pH, there is a change in the fundamental shape of the M-wave involving a physiological process other than pH.

Preliminary Results/Future Plans—A second series of investigations to study the effects of compensated (buffered) and uncompensated acidosis on diaphragm function and EMG parameters was conducted on an additional 12 preparations. Although the data have not been completely analyzed, preliminary results indicate that these conditions have a significant effect on the EMG signal and force. We have observed that compensated acidosis actually improves the muscle's ability to generate force during the short duration of the contraction. Further analysis is planned to correlate the EMG signal and force behavior for both studies.

Recent Publications Resulting from This Research

Biochemical and Myoelectric Events During Fatigue. DeLuca CJ et al., presented at the 19th Annual Meeting of the Society for Neuroscience, Phoenix, 1989.

[286a] Low Back Pain and Muscle Fatigue

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Delft University of Technology, Delft, The Netherlands

Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 2); Liberty Mutual Insurance Company

Purpose—As many as 75 million Americans now suffer from severe low back pain and each year 7 million more people develop this problem. Despite the many millions of dollars spent on innumerable treatments for the back, the majority of patients have chronic, recurring symptoms. Improved methods for assessing back disorders could help to diminish the prevalence and the financial burden of this disabling condition. We have developed and are implementing a technique to provide the clinician with an objective index with which to measure treatment outcome for lower back musculature. This technique estimates the fatigue rate of contracting muscles by surface-detected EMG signals. The dynamic interaction of synergistic back muscles during fatiguing contractions may be represented by “fatigue patterns” created by the frequency shifts in various muscles. Differences in these patterns associated with low back disorders may represent functional disturbances in back muscles.

Methodology—The EMG measurement technique for the lower back was recently redesigned to meet the needs of the clinical environment where it is presently used as a research instrument. This technique, called the Back Analysis System (BAS), is described in Part 3 of this report. Our goal is to develop a database large enough for future diagnostic capabilities. Numerous tests are being conducted at several clinical sites using a standardized protocol that includes both high and low force levels of contraction. A brief contraction is repeated one minute following these tests to measure the recovery process from fatigue of lower back muscles.

Progress/Preliminary Results—Our assessment technique targets specific subcategories of low back pain. For example, we are testing patients with at least a 6-month history of chronic back pain but no radiographic evidence of spinal abnormalities. Unlike our previous pilot studies, we are including more aged and female subjects in these tests. We have also begun testing patients with structural spinal disorders in the subacute and chronic stages of low back pain. An activity-level survey and pain questionnaire have been included in the standard protocol. Conventional measures of spinal mobility and static strength have been obtained and compared to EMG median frequency measurements. Our results to date indicate that the EMG parameters are able to discriminate low back pain patients from pain-free control subjects, whereas conventional methods are not.

Recent Publications Resulting from This Research

Lumbar Muscle Fatigue and Chronic Lower Back Pain.

Roy SH, DeLuca CJ, Casavant DA, *Spine* 14(9):992-1001, 1989.

Lumbar Muscle Fatigue and Chronic Lower Back Pain. Roy SH, DeLuca CJ, Casavant DA, presented at the Annual Combined Sections Meeting of the APTA, Honolulu, 1989.

Lumbar Muscle Fatigue and Chronic Lower Back Pain. Roy SH, DeLuca CJ, Casavant DA, presented at the Italian/American Medical Conference, Bologna, Italy; the 20th International Symposium on Rehabilitation Research of the Handicapped and the Developmentally Disabled, Cairo, Egypt; the 21st International Conference on Rehabilitation and Developmental Disabilities, Milan, Italy, 1989.

[286b] Back Analysis System (BAS)

C.J. DeLuca; D. Gilmore; S.H. Roy

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 3); Liberty Mutual Insurance Company

Purpose—During the past 3 years, we have continuously refined our methods used to evaluate muscle performance in individuals with and without low back pain. A key component in these investigations has been the Back

Analysis System (BAS), a computerized EMG spectral analysis system coupled to a pelvic restraining device.

The BAS and its associated apparatus is designed to stabilize and isolate the trunk musculature and analyze

the patterns of muscle activity observed during isometric contraction of the back muscles. The specialized restraint apparatus is designed to immobilize the pelvis and assure that the contribution to the flexion and extension forces is limited to the muscles of the lower back. The system configuration and experimental protocols which may be selected via software permit researchers to tailor the BAS to a variety of back performance evaluations.

Progress—Over 200 individuals have been evaluated using the BAS, generating a research database consisting

of “normals,” athletes, and individuals with muscular dysfunction such as fibromyalgia. To augment this database and expand the application of the System to clinical settings, a BAS has been placed at Boston City Hospital as part of a collaborative project with their Department of Orthopedics.

This system was demonstrated for the VA Congressional Subcommittee on Hospitals and Health Care in Washington, DC, in September 1989.

[286c] Back Assessment of Athletes from Varsity and Freshman Crew Teams

C.J. DeLuca; M. Emley; S.H. Roy; L. Snyder-Mackler; A. Klein; J. Vogelaar

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 4); Liberty Mutual Insurance Company

Purpose—The purpose of this study is to determine whether correct identification of low back pain can be accomplished in a mixed population of novice and experienced freshman rowers based on EMG spectral parameters from lumbar muscles. By repeating the BAS test procedures twice a year until the novice rowers complete their varsity year, we will be able to validate the technique further as a screening device for low back pain. The effects of athletic training and exercise on EMG parameters of the lower back will also be assessed.

Progress—Twenty-five members of the Boston University men's freshman crew team have participated in this study to date. As new freshman crew members join the team, they will be recruited for the study.

Preliminary Results/Implications—In the fall 1988 rowing season, we completed the preliminary phase of

testing. The results from this part of the study indicated that EMG signal spectral analysis can correctly identify rowers with low back pain from a mixed population of novice and experienced freshman rowers. The crew team was retested in the spring, following a winter training period. The preliminary results show an increase in static strength of back extensors and an improvement in fatigability for the novice rowers, but not for the experienced rowers. However, novice rowers after one year of training did not achieve the same level of maximal voluntary contraction or resistance to fatigue as the more experienced rowers. These findings indicate that extensive training can modify the frequency spectrum of the EMG signal. We hope that our data and analysis will be useful to the individual athletes and their coach as an objective measure for designing and assessing training procedures.

[286d] Back Assessment in Patients with Fibromyalgia

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 5); National Institutes of Health; Liberty Mutual Insurance Company

Purpose—Fibromyalgia, also called fibrositis, is increasingly recognized as one of the most common causes of chronic musculoskeletal pain and fatigue. It is classified within the spectrum of generalized nonarticular rheumatism and affects between three and six million Americans. The most compelling pathophysiologic evidence for objective abnormalities in fibromyalgia has come from recent studies of muscle histology and physiology. These results, although not conclusive, have prompted rheumatologists at the Arthritis Center of The University Hospital to study the muscular component of fibromyalgia via objective fatigue measures developed in our laboratory. This interest follows a number of years of clinical research to help delineate fibromyalgia from other similar disorders.

Preliminary Results—A study was completed in which 10 patients with fibromyalgia and 10 control patients

were tested for muscle function in the lower back. The BAS was used to identify abnormal patterns of fatigue during sustained isometric contractions and recovery. Abnormal muscle fatigue was not present in the lower back muscles of fibromyalgia patients. Conversely, patients with chronic low back pain but no diagnosis of fibromyalgia demonstrated abnormal fatigue at the L2 and L5 lumbar levels in the paraspinal muscles. More comprehensive studies involving lower-limb and shoulder muscles of patients with fibromyalgia are under way.

Recent Publications Resulting from This Research

Back Assessment in Patients with Fibromyalgia. DeLuca CJ et al., presented at the 1st International Symposium on Myofascial Pain and Fibromyalgia, Minneapolis, 1989.

[286e] Mechanical Recruitment of Low Back Muscles

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 6); Boston University (Patricia Harris Fellowship)

Purpose—By assuming that the EMG signal level of a given muscle reflects its force output, a physical task that requires a constant muscle force output level can be designed. If the EMG signal level recorded from that muscle is found to be constant, a relationship between the predicted force level and the measured EMG signal level can be established. Such an experiment presents a new level of testing of the biomechanical model and, if successful, could further strengthen the relationship between mechanical loading and lumbar muscle activation.

Progress—Our biomechanical model of the lower back, developed during the past 3 years, was further studied. The muscle activity surfaces that summarize the muscular

force of each of the 22 different muscles that cross the L3 level were analyzed to identify external loading combinations that require a constant muscular force response. We can therefore predict that a given quasi-static loading exercise involving moving a hand-held weight in front of the body will require a constant force output of a given muscle in the lumbar region. Such an exercise can be described by an isoforce curve in the "loading plane" (a mathematical plane whose axes are the flexion and lateral bending moments). By describing the isoforce curves of a given muscle on the loading plane, a map of the predicted activation levels of that muscle is created. Mathematically, these curves were derived from different lumbar muscles by intersecting the muscle activity surface and a plane representing a constant force level.

Recent Publications Resulting from This Research

Theoretical Predictions and Experimental Validation. Ladin Z, Murthy KR, DeLuca CJ, *Spine* 14(9):927-938, 1989.

Awards

Mechanical Recruitment of Low-Back Muscles. Volvo Award in Biomechanics, 1989.

[286f] The Lumbarator: A Real-Time Simulator of Lumbar Muscle Force Distribution

C.J. DeLuca; Z. Ladin; S. Guha

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 7)

Purpose—The purpose of this study was to devise a prototype system for the design of weightholding exercises and to study the muscular load-distribution resulting from those exercises.

Results—The prototype system has been completed. The graphic display of the system involves two screens: an exercise-design screen and a muscle-force display screen. The exercise-design screen is composed of four windows that describe the four different views of the human model. The middle window is the load and posture-selection window. Using the mouse, loads for the left and right hands can be selected. By placing the mouse on the angle selection window, a series of points representing elbow angle and shoulder angle can be selected for both hands, representing a complete quasi-static exercise. Based on the elbow angle, shoulder angle, and load in left and right hands for each position in the quasi-static exercise, flexion moment and lateral bending are calculated. The moment combination is used to access the database of the muscle activity surfaces for all 22 muscles, and the individual muscle forces that correspond to that loading condition are calculated.

The muscle-force screen displays in real-time the distribution of muscle forces in the lower back in

response to gravitational loading. Using a precalculated database of muscle activity surfaces for 22 muscles crossing the L3 level in the lumbar region, the system displays the load distribution among all the different muscles using a color or a gray-level scale and, therefore, enables the user to study immediately the effect of given quasi-static exercises on muscle force distribution in all the muscles of the cross-section of interest. The forces are displayed on the right side of the screen using a color or a gray-level scale. By placing the mouse cursor inside the table, the "switching curve" of that particular muscle can be displayed on the "loading plane." The "switching curve" separates the loading combination that will activate the muscle (on one side of the curve) from those that will not (on the other side of the curve). Thus, using the mouse, quasi-static exercise can be designed which would simulate, in real-time, variations in individual muscle forces.

Recent Publications Resulting from This Research

The Lumbarator: A Real-Time Simulator of Lumbar Muscle Force Distribution. DeLuca CJ, Ladin Z, Guha S, in *Proceedings of the 12th International Congress of Biomechanics*, Los Angeles, 1989.

[287] The Myoelectric Signal Decomposition Technique

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 1)

Purpose—Myoelectric (ME) signal decomposition is a technique for studying the firing behavior of individual motor units, as well as the interactions of populations of simultaneously active motor units. This technique consists of three main parts: signal detection, acquisition,

and decomposition. Refinements to this technique for analyzing motor unit firing behavior have focused on detecting and acquiring better quality signals and decomposing these signals with greater speed and accuracy.

Progress/Preliminary Results—We continued to implement a number of improvements on the decomposition process. New techniques were developed to graphically display intervals of motor unit activity while our specialized multichannel needle electrode is positioned in the muscle. Also, we experimented with alternative approaches for automatically decomposing ME signals and some new post-decomposition algorithms for monitoring

and displaying the results of our decomposition technique. These analysis routines have facilitated our studies of synchronous motor unit firing, common modulation of motor unit firings, "common drive," macro-electromyography, and the effects of muscular fatigue on motor unit firing behavior. Together with our improvements in data acquisition, these changes have decreased the time required to collect and analyze high quality data.

[287a] Motor Unit Firing Behavior in Older Adults

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 2); Liberty Mutual Insurance Company

Purpose—The NeuroMuscular Research Center has embarked on a long-term study to determine the changes in neuromuscular and central nervous system function affecting older adults. Our goal is to determine alternative intervention strategies to improve functional status. Toward this end, we have been exploring motor unit firing behavior in the aged. Our experiments indicate that some of the observations made in younger individuals match those seen in the elders. For example, motor unit firing rates tend to be higher in small muscles than in large muscles. However, in some individuals the force at which a motor unit is activated does not match the force

at which it is deactivated. Our current studies involve the relationship among macro-EMG area, axonal conduction velocity, and recruitment threshold in order to determine how the known changes in the morphology of the motor unit affect firing behavior.

Recent Publications Resulting from This Research

Unusual Motor Unit Firing Behavior in Older Adults. Kamen G, DeLuca CJ, *Brain Res* 482(1):136-140, 1989.

Motor Unit Firing Behavior in the Aged. Kamen G, DeLuca CJ, in *Computer-Aided Electromyography and Expert Systems*, 231-239, J.E. Desmedt (Ed.). Amsterdam: Elsevier Science Publishers B.V., 1989.

[287b] Recurrent Inhibition in Older Adults

C.J. DeLuca; G. Kamen; S. Sison; K.R. Murthy

NeuroMuscular Research Center, Boston, MA 02215

Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 3); Liberty Mutual Insurance Company; Boston University

Purpose—In our effort to improve our understanding of spinal reflex systems in the elderly, we have been studying recurrent inhibition in older adults. Our previous work indicates that under some conditions the integrity of both short- and long-latency reflexes may be improved in older adults. Our working hypothesis is that these changes may indicate that some underlying neural compensation is possible in the spinal reflex center.

Methodology/Progress—To test this idea, we have undertaken a study of an important neural pathway affecting the motoneuron—the recurrent inhibitory system mediated by the Renshaw cell. This neural system is important in a number of motor tasks including those

involving various levels of cocontraction of agonist and antagonist muscles and oscillating activity such as walking. The technique utilized paired conditioning-test electrical stimuli delivered to the tibial nerve during conditions involving various degrees of voluntary effort. Our early experiments have demonstrated satisfactory test-retest reliability and we are preparing to begin comparisons of results from aged and college-age adults.

Recent Publications Resulting from This Research

Recurrent Inhibition in Older Adults. Kamen G et al., presented at the Annual Meeting of the American Academy of Clinical Neurophysiology, Boston, 1989.

[287c] The Role of Cutaneous Receptors in Motor Unit Firing Behavior

C.J. DeLuca; Y. Masakado; G. Kamen; A. Roy

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 4); Liberty Mutual Insurance Company

Purpose—In previous experiments, we demonstrated that desensitizing the skin through the application of a topical anesthetic can have a marked effect on motor unit firing rate and recruitment threshold. This study sought to further investigate the role of cutaneous receptors on motor unit firing behavior through the use of electrical stimulation of cutaneous receptors.

Results/Future Plans—Myoelectric signals were obtained from the first dorsal interosseous muscle while the subject followed a trajectory on a monitor, requiring the production of up to 50% of maximal voluntary

contraction (MVC). These signals were decomposed into constituent motor unit action potential trains, and the recruitment thresholds and maximal firing rates (at 50% MVC) were determined before and after 3 minutes of skin stimulation at an intensity equivalent to three times perceptual threshold. For most motor units, the force at which units were recruited increased while maximal firing rate decreased. However, the effect was less dramatic than that observed by other investigators. We plan to investigate and determine whether skin receptors have similar influence on both tonic and phasic motoneurons.

[288] Characterization of Back Muscles by Means of Electrical Stimulation

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Sponsor: VA Rehabilitation Research and Development Service (Project #B595-RA); National Research Council of Italy; Liberty Mutual Insurance Company

Purpose—The objective of this project is to assess the feasibility of back muscle characterization by means of electrical stimulation techniques. If feasible, the technique would be relevant to our work on low back pain.

Preliminary Results—Thirty-five experiments were performed on 19 healthy male subjects. The longissimus dorsi (LD) and the iliocostalis lumborum (ILC) muscles were individually stimulated at two intensities and two frequencies while myoelectric signals were detected from both muscles. Conduction velocity (CV) and mean and median frequency (MNF and MDF) were estimated. Selective stimulation of a single muscle was not always possible. Partial data analysis shows that out of 42 contractions, 10 showed activation of the LD during stimulation of the ILC and 8 showed activation of the ILC during stimulation of the LD. In 17 contractions, no indications of either coactivation or crosstalk could be detected, and

crosstalk (without coactivation) could be detected in only two contractions.

Signals detected on the back muscles were almost an order of magnitude smaller than those detected on the tibialis anterior (TA). The initial CV of both back muscles was higher than in the TA, suggesting either different fiber type and/or size distribution, or bias errors due to electrode-fibers misalignments. Initial MDF was slightly higher in the TA, probably because of the thinner layer of fat and fascia interposed between the TA and the skin. As observed in the TA, the recruitment order of motor units of the back muscles was not consistent, showing either increase or decrease of initial CV as stimulation amplitude was increased. During fatiguing contractions, CV decreased faster in the TA than in either the LD or ILC and decreased faster in the LD than in the ILC.

Future Plans/Implications—The technique needs improvement in order to obtain more consistent and

acceptable signals from different subjects; repeatability studies must be performed to assess intra-subject variability. However, this method shows promise for the selective activation and characterization of individual back muscles.

Recent Publications Resulting from This Research

Characterization of Back Muscles by Means of Electrical Stimulation. DeLuca CJ et al., in Proceedings of the 11th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 1041-1042, Seattle, 1989.

[289] Control Properties of Lower Back Muscles

C.J. DeLuca; K.R. Murthy; T. Sciascia; G. Kamen

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Sponsor: VA Rehabilitation Research and Development Service (Project #B596-RA, Part 1)

Purpose—Our recent investigations have used surface electrodes to study the performance of lower back muscles in an effort to address the issues surrounding low back pain. In as much as these muscles are not well understood, we have also become interested in characterizing the properties of these muscles. Thus, this study focuses on the manner in which motor units are controlled during contractions of muscles of the lower back.

Since it was not clear that our indwelling needle electrode recording technique could be implemented in the lower back, a pilot experiment was performed to assess the feasibility of such an approach. We were able

to successfully extract the motor unit firing behavior of the longissimus muscle in this experiment. Having demonstrated the ability to acquire motor unit myoelectric signals from back muscles, we plan to begin a detailed study of the firing behavior of low back muscles in an effort to characterize the control properties of these muscles. We hope that these data will allow us to determine whether the muscles of the lower back are controlled in a manner different from the control of other previously studied skeletal muscles. Moreover, these studies will also assist our ongoing investigations involving biomechanical modeling of the lower back by reducing the inherent redundancies in the model.

[289a] Fundamental Analysis of Postural Sway

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Sponsor: VA Rehabilitation Research and Development Service (Project #B596-RA, Part 2); Whitaker Foundation; Liberty Mutual Insurance Company

Purpose—The task of maintaining an upright posture involves the integration of sensory information from three different systems: the visual system, the vestibular system, and the proprioceptive system. The multiple number of muscles involved and the inherent instability in the task cause the center of gravity of the body and the center of pressure underneath the feet to move even while the individual is trying to maintain a fixed posture. A stochastic analysis of the motion of the center of pressure as recorded by a force-plate revealed the existence of two components: a random component and a periodic circular component.

The random component is characteristic of the motion of particles performing random movement (e.g.,

a diffusing molecule). The periodic component is characteristic of the motion of a particle performing a circular motion at a constant angular velocity. A theoretical model that combines the two components is suggested as a conceptual description of the two elements identified in actual measurements of the motion of the center of pressure. A new parameter that quantifies the relationship between the periodic and the random components was developed. This parameter is being examined as an objective measure of the degree of randomness that characterizes the postural control capacity of an individual subject.

[290] Experimental Investigations of Common Drive Behavior in Human Motor Units

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—We have described in previous reports a novel phenomenon of motor unit firing behavior in which concurrently active motor units modulate their firing rates in a unified fashion. Our goal in this experiment was to further our understanding of this common drive behavior.

Progress/Results—The muscle spindle has been implicated as one possible source of this common firing rate fluctuation. We endeavored to measure motor unit firing rates in a facial muscle devoid of muscle spindles, the

orbicularis oris. Approximately 21 motor units were analyzed from a total of 5 subjects. The results indicate that common drive behavior can indeed be observed in the absence of muscle spindles. While muscle spindles may contribute to this firing rate fluctuation in other muscles, it is clear that this effect in muscles devoid of muscle spindles is mediated by skin receptors, or other stretch-type receptors, or some central nervous mechanism.

This work was presented at the annual meeting of the Society for Neuroscience, Phoenix, AZ, 1989.

[291] Muscle Fatigue Correlates for Concurrent Myoelectric and NMR Measurements

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—The physiological correlates to the observable shift in the electromyography (EMG) signal frequency spectrum during fatigue are not completely understood. Although it is widely accepted that this spectral shift is related to a slowing of EMG signal conduction velocity, the extent to which this phenomenon is related to a change in pH or energy sources within the muscle is not clear. The precise relationship between cellular biochemical events and the electrical manifestation of muscular fatigue has eluded investigators. One of the principal obstacles has been the invasive nature of available techniques to measure intramuscular substrates and metabolites. However, with recent technical advances in phosphorous nuclear magnetic resonance spectroscopy (³¹P-NMR), intramuscular pH, and other cellular biochemical events can be noninvasively assessed in resting or exercising muscle.

Progress—We have completed the modification and testing of myoelectric and torque measuring devices to ensure compatibility with the high magnetic fields

characteristic of NMR instrumentation. This work was pursued through the collaborative efforts of the NeuroMuscular Research Center and the Nuclear Magnetic Resonance Laboratory at the Brigham and Women's Hospital.

Results/Implications—Preliminary measurements have been completed for 2 subjects (a total of 10 tests) to identify optimal contractile force levels and test durations for establishing a protocol that will accommodate the signal requirements of both methodologies. This procedure has enabled us to monitor the change in median frequency as a function of time during and following a sustained fatiguing contraction. The median frequency behavior has been compared to concurrent measures of pH and muscular high-energy phosphate following pilot studies on the tibialis anterior, gastrocnemius, and upper trapezius muscles.

Future Plans—Future goals include developing protocols to establish causality between physiological measures and spectral parameters of the myoelectric signal.

[292] Myoelectric Changes During Fatigue

C.J. DeLuca; N. Paul; G. Kamen

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—Many studies have shown that during a sustained muscle contraction there is a shift in the myoelectric signal spectrum toward lower frequencies. This shift has been attributed to a decrease in the velocity of propagation of individual muscle fiber action potentials. However, conduction velocity changes measured on the surface of the muscle cannot completely account for the observed spectral shifts. This study analyzed the myoelectric signal during fatigue with both indwelling needle and surface electrodes in order to compare results obtained both on the surface and inside the muscle.

Preliminary Results/Future Plans—As observed in previous experiments, this study showed that the rate of

decline in median frequency was greater than that seen in conduction velocity. The selective needle signals were decomposed using myoelectric signal processing and decomposition algorithms, in order to analyze the effects of fatigue on individual motor units. Preliminary analysis shows that there was no increase in synchronous firing behavior, and there was no evidence of change in the number of active motor units near the recording electrode during fatigue.

The selective needle signals are currently being analyzed for relative changes in individual motor unit conduction velocity, which will be compared to changes in spectral parameters of these myoelectric signals to see if the relationship detected at the surface is also observed within the muscle.

[293] Muscle Fatigue Monitor (MFM) Update

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—The concept of plotting changes in the spectra of the myoelectric signal as an indicator of fatigue had its origins over 20 years ago. However, practical signal processing techniques to measure this phenomenon have only recently emerged as a result of advances in electronics and computer technologies. The Muscle Fatigue Monitor (MFM) conceived by our Center has similarly evolved from a crude prototype into a sophisticated computer-based system capable of processing 10 channels of myoelectric data in real time. The present system allows researchers to investigate the fatigue process of more complex muscular activities, such as those involving the muscles of the lower back or of the hand and wrist. During the past 2 years, this system has been used extensively in our Muscle Fatigue Laboratory to generate a detailed picture of back performance and its relationship to episodic back pain. This research application has

proven to be a key element in obtaining consistent, objective, and reliable measurement of muscular activity from the lower back.

Progress—In an effort to expand applications into new environments, we have installed additional MFM systems in both clinical and university settings. Units have been placed at Boston City Hospital, Rush-Presbyterian-St. Luke's Medical Center, Queen's University in Canada, and Michigan State University. A fifth MFM system, installed at the Liberty Mutual Research Center, will be used to investigate fatigue of the hand and wrist in a simulated industrial environment.

Future Plans—The upcoming year will focus on the continued integration of the MFM technology in clinical applications.

[294] Electromyographic Spectrum Analysis of Paraspinal Muscles: Changes Following Physical Training

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Sponsor: *Medical Research Council of Canada; Physicians' Services, Inc. Foundation; Ontario Ministry of Health*

Purpose—It has been suggested that electromyographic power spectrum analysis (EMG-PS) of the paraspinal muscles has two major clinical purposes in the area of low back pain: 1) patient status evaluation; and, 2) treatment outcome evaluation. While the usefulness of EMG-PS in differentiating back pain patients from controls has been demonstrated, no information is available on the sensitivity of this methodology to muscle adaptations resulting from physical therapy (e.g., increased oxygenation, metabolic capacity, cross-sectional muscle fiber area). We are investigating the relationship between changes in fitness parameters (related to such adaptations) and changes in EMG-PS parameters in two studies.

Progress—*Study 1.* Previously sedentary healthy women are undergoing fitness tests (which determine aerobic capacity, strength, flexibility, body composition), and EMG-PS of the iliocostalis and multifidus muscles, before and after a 12-week period, during which they volunteer to attend 3 to 5 fitness classes per week. These data are being compared to those of control subjects who remain sedentary.

Study 2. A similar investigation is being carried out with low back pain sufferers who participate in the University Back School program (10-week duration).

[295] Electrode Array Signal Processing

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Sponsor: *Medical Research Council of Canada*

Purpose—The main purpose of this study is to improve evoked response measurement signal-to-noise ratio (SNR) by the use of array beamforming.

Progress/Results—A delay and sum array beamformer has been analyzed and implemented. The results demonstrate that the array can, depending on the cross-channel correlation, improve SNR by a factor equal to the number of electrodes in the array.

Recent Publications Resulting from This Research

A Multi-Electrode Array for the Acquisition of Somatosensory Evoked Potentials. McKinley CA, Masters thesis, Department of Electrical Engineering, University of New Brunswick, 1989.

A Multi-Electrode Array in Ensemble Averaging of Evoked Potentials. McKinley C, Parker PA, in Proceedings of the Canadian Medical and Biological Engineering Conference, Toronto, 75, 1989.

A Beamformer for the Acquisition of Evoked Potentials. McKinley CA, Parker PA, IEEE Trans Biomed Eng (accepted for publication).

[296] Postural Muscle Adaptability During Prolonged Spaceflight

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Sponsor: *National Aeronautics and Space Administration (NASA); NeuroMuscular Research Center*

Purpose—The Center's experience in implementing techniques to measure muscle fatigue noninvasively and objectively will be applied to a comprehensive investigation of the effects of prolonged spaceflight (microgravity)

on the vestibular and motor systems of the body. This project is a component of the NASA shuttle program involving the Spacelab Life Science (SLS-01) mission. This mission represents the first shuttle flight dedicated

entirely to the medical and biological effects of spaceflight. Our contribution to the project will be directed at electromyographic (EMG) measurements of postural muscle adaptation to microgravity.

Progress—A protocol using surface EMG was formulated and tested to evaluate changes in EMG spectral measures of fatigue and conduction velocity for several postural muscles of the lower limb.

Future Plans/Implications—Measurements will be conducted preflight and immediately postflight on

members of the shuttle crew. The Muscle Fatigue Monitor and associated signal-processing software will be used to measure EMG spectral parameters and conduction velocity. When completed, we hope to demonstrate the use of the technique for documenting the adaptability of postural muscles to microgravity. This information will complement related studies on vestibular function and spaceflight conducted by Massachusetts Institute of Technology. Successful development of prophylactic exercises for future spaceflight will most likely be dependent on objective measures of this kind.

[297] Mechanism of Torque Generation in the Frog Hindlimb

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Sponsor: *National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health*

Purpose—The objective of this project was to understand the relationship between muscle and joint properties during torque generation. Muscle sarcomere length and moment arm were measured in the frog hindlimb (*Rana pipiens*) at 10-degree knee and hip joint angle increments. Knee and hip torque were also directly measured over the same range.

Results/Implications—The major finding of this study was that the joint angle at which muscle force was maximum, was neither the joint angle at which moment arm

was maximum, nor the angle at which joint torque was maximum. These data suggest that muscle fiber length relative to moment arm magnitude have a major impact on the nature of torque generation at a particular joint.

Recent Publications Resulting from This Research

Hypothesis: Biarticular Muscles Transfer Moments Between Joints.
Lieber RL, Dev Med Child Neurol 32:456-458, 1990.
Interaction Between Semitendinosus Muscle and Knee and Hip Joints During Torque Production in the Frog Hindlimb. Mai MT, Lieber RL, J Biomech 23:271-279, 1990.

[298] Physiological Significance of Tendon Compliance

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Sponsor: *National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health*

Purpose/Methodology—The purpose of this study was to understand the relationship between tendon and muscle mechanical properties. We measured tendon properties during passive loading and during isometric muscle contraction. The pelvis-tendon-ST muscle-tendon-tibia complex (BTMTB complex) was isolated from 10 grass frogs (*Rana pipiens*). Dye lines were applied to mark regions of the tendon, aponeurosis, and muscle. Pelvic and tibial bones were clamped into a testing jig immersed in physiological saline (21 degrees C). The muscle was

maximally activated to measure maximum contractile tension (P_0). The BTMTB complex was then loaded at a constant rate of about 3% $P_{0/s}$ while measuring force and videotaping the applied dye lines. Using load-time and strain-time values (as measured off-line using a video dimensional analyzer), tendon load-strain, and stress-strain relations were generated.

Results/Implications—Tendon strain corresponding to P_0 was approximately 3%. Tendon stress at P_0 was

approximately 2 MPa. In addition, at physiological contraction velocities, the tendon was relatively stiffer, suggesting that the viscoelastic properties were significant, even at low velocities. The results also demonstrate that tendon compliance is sizeable even in the physiological range, and cannot be assumed to be negligible.

Recent Publications Resulting from This Research

- Measurement of Frog Semitendinosus Force, Tendon Load-Deformation and Load-Strain Properties. Lieber RL, Leonard ME, J Biomech 22:1048, 1989.
Frog Semitendinosus Tendon Mechanical Properties During Passive Loading and Active Muscle Contraction. Lieber RL, Trestik CL, Leonard ME, J Biomech (in press).

[299] Skeletal Muscle Architectural Design

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Sponsor: *National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health*

Purpose/Methodology—The purpose of this project was to elucidate the design of various mammalian skeletal muscles. In the rabbit hindlimb, the detailed fiber arrangement of 26 muscles was measured and submitted for discriminant analysis for determination of the structural factors which most strongly differ between functional groups.

Results/Implications—In general, hamstrings and dorsiflexors were composed of relatively long fibers with relatively low physiological cross-sectional areas. Conversely, the antigravity quadriceps and plantarflexors were generally more highly pennated, with relatively short fibers and large cross-sectional areas. Similar degrees of specialization were observed in the human

forearm. These data indicate that skeletal muscles are “smart” in that they perform the needed task (force or excursion/velocity) by virtue of their intrinsic design, and not by virtue of extremely sophisticated sets of neural command signals.

Recent Publications Resulting from This Research

- Architecture of Selected Human Forearm Muscles: Functional Implications for Tendon Transfer. Lieber RL, Fazeli BM, Botte MJ, in Transactions of the 35th Orthotics Research Society, 14:198, 1989.
Skeletal Muscle Architecture of the Rabbit Hindlimb: Functional Implications of Muscle Design. Lieber RL, Blevins FT, J Morphol 199:93-101, 1989.
Architecture of Selected Wrist Flexor and Extensor Muscles. Lieber RL, Fizele BM, Botte MJ, J Hand Surg 15:244-250, 1990.

[300] Selective Muscle Fiber Damage Due to Eccentric Contraction

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Sponsor: *National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health*

Purpose/Methodology—The purpose of this project was to determine the mechanism of damage in muscle fibers from the rabbit tibialis anterior. Muscles were cyclically stretched 25% of their fiber length every 2 seconds for 30 minutes.

Results/Implications—Force declined significantly after eccentric contraction (EC) compared to either isometric contraction or passive stretch. In addition, fibers from EC muscles demonstrated focal regions of ultrastructural abnormalities and light microscopic damage to the fast-glycolytic (FG) fibers. These data suggest that the FG

fibers might be particularly vulnerable to EC-induced damage and may also explain why previous training attenuates the magnitude of EC-induced damage.

Recent Publications Resulting from This Research

- The Effect of Varied Strain on Muscle Damage During Eccentric Exercise of the Rabbit Tibialis Anterior. Lieber RL et al., in Transactions of the 35th Orthotics Research Society, 14:295, 1989.
Immunohistochemical Identification of Cytoskeletal Damage in Muscle Cells Subjected to Eccentric Exercise. Lieber RL, Friden JO, in Transactions of the 36th Orthotics Research Society, 36:542, 1990.

[301] Utility and Physiology of Botulinum Toxin for Involuntary Movement Disorders

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose/Methodology—Botulinum toxin injected in small doses directly into muscle binds to the neuromuscular junction and inactivates it for approximately 3 months. This treatment has been demonstrated to be useful for strabismus and blepharospasm, but the mechanism of action is not completely understood. Studies of utility of botulinum toxin have been carried out in spasmodic dysphonia and writer's cramp and its variants (such as pianist's cramp). Treatment appeared effective in both, and we are enlarging our experience with writer's cramp to see if we can determine which patients are more

likely to improve. A double-blind trial was started for writer's cramp.

Progress/Results—Studies of the physiology of the mode of action have been carried out in spasmodic dysphonia, writer's cramp, blepharospasm, and hemifacial spasm. These studies show that the major effect of botulinum toxin is to weaken the muscle that is in spasm. Electromyogram studies in writer's cramp, blepharospasm, and hemifacial spasm show that spasms continue, but muscles are ineffective. No other changes in physiology were identified.

[302] Biological Signal Processing

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Sponsor: Natural Sciences and Engineering Research Council of Canada

Purpose—Our purpose was to determine the effects of various physiological parameters of skeletal muscle on myoelectric signal and the control performance of myoelectric control systems.

Progress—To date, an extensive study has been carried out to investigate the effects of firing rate statistics, endplate dispersion, action potential shape, and number of units on the control performance of a myoelectric control system. The performance equations have been derived and the results verified by simulation and *in vivo* experimental work.

Recent Publications Resulting from This Research

Analysis of the Myoelectric Communication Channel. Zhang YT, PhD diss., University of New Brunswick, 1990.

A Study of the Effects of Motor Unit Recruitment and Firing Statistics on the Signal to Noise Ratio of a Myoelectric Control Channel. Zhang YT, Parker PA, Scott RN, Med Biol Eng Comput 28(3):225-231, 1990.

Control Performance Characteristics of Myoelectric Signal with Additive Interference. Zhang YT, Parker PA, Scott RN, Med Biol Eng Comput (accepted for publication).

[303] Coordination of Muscles in Gait

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Sponsor: Netherlands Organization for Research, Foundation of Biophysics

Purpose—The coordination of lower limb muscles has been studied when one is jumping up and down and when bicycling. Rules for the function of biarticular

muscles were found. This project is to ascertain if these rules are applicable during normal walking and running.

Progress/Results—Biarticular muscles play a unique role in transporting rotational energy from proximal to distal segments when a person jumps up and down. The muscles contribute to the mechanical goal of the movement—maximizing effective power at take-off. They compensate for the diminishing contribution to translation of the body's center of gravity by extension (rotation) of lower limb segments.

Timing of the activation of these muscles, as well as the fact that they co-contract with their antagonists, is important. In bicycling, it appeared essential that such co-contractions were instrumental in producing thrust, as well as direction of movement in the extending limb.

We have tried to validate these concepts in human walking and running by experimenting and modeling. In gait, biarticular hamstring and rectus femoris muscles are active in early stance. They co-contract with monarticular hip and knee extensors, and tune hip and knee movements while the leg is shortening and lengthening (knee flexion), regulating the level of potential energy.

This result will be compared with those of the running and jumping studies.

Future Plans—Jumping up and down, and the timing and geometrical properties of the system will be analyzed by modeling. A model (SPACAR) has been developed that applies finite element analytic instruments to problems of dynamics. Force platform, movement, and the electromyographic registration of long jumps, running, and walking will be analyzed using this model.

Recent Publications Resulting from This Research

The Unique Action of Bi-Articular Muscles in Leg Extensions. Van Ingen Schenau GJ, Bobbert MF, Van Soest AJ, in *Multiple Muscle Systems: Biomechanics and Movement Organizations*, 639-652, J. Winters, S.L.-Y. Woo (Eds.). New York: Springer-Verlag, 1990.

The Activation of Mono- and Bi-Articular Muscles in Multi-Joint Movements. Gielen S et al., in *Multiple Muscle Systems: Biomechanics and Movement Organizations*, 302-311, J. Winters, S.L.-Y. Woo (Eds.). New York: Springer-Verlag, 1990.

[304] Skeletal Muscle Reaction to Immobilization

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Sponsor: *Netherlands Organization for Research, Foundation for Biological Sciences*

Purpose—The purpose of this study was to predict the reaction of human skeletal muscle to immobilization regarding length, duration of immobilization period, and position of the limbs.

Progress—A muscle model, relating the architecture of the skeletal muscle to its functional capacity, was formulated and experimentally determined on rat calf muscle and various others. Application to human calf muscle, using morphological data of human cadavers was done. The model was also applied in a description of muscular growth. It is now being used in analyzing the effects of various periods of immobilization in different positions, leading to differing muscle lengths.

The work is part of a program on "form, function and coordination of skeletal muscles," in which we have tried to relate experimental analysis of animal muscular function to real life human movements in vertical jumping and running.

Results—Effects of 4- to 6-weeks immobilization of calf muscles in growing rats were studied. Slow twitch soleus muscle followed the general rule: sarcomeres were lost during immobilization in shortened position. Predominantly fast and pennated gastrocnemius muscle reacted with alterations in muscle fiber length and sarcomere number, as well as alterations in aponeurotic length. Depending on the period of immobilization, these reactions resulted in abnormal length-force relations normalized to optimum length and maximal force at that length after 4 weeks. After 6 weeks these relations were normal, suggesting that the tissues of the muscle were harmoniously working together again. In short-term immobilized muscles, the reactions of muscular and connective tissue components in pennated muscle were not functionally balanced.

Future Plans—The interrelationships of muscular and connective tissue in growing and functioning muscle will be studied in more detail.

Recent Publications Resulting from This Research

Properties of the Tendinous and Series Elastic Component of EDL Muscle-Tendon Complex of the Rat. Ettema GJC, Huijing PA, J Biomech 22:1209-1215, 1989.

Architecture and Elastic Properties of the Series Elastic Element of Muscle-Tendon Complex. Ettema GJC, Huijing PA, in

Multiple Muscle Systems: Biomechanics and Movement Organizations, 57-68, J.M. Winters, S.L.-Y. Woo (Eds.). New York: Springer-Verlag, 1990.

Series Elastic Properties and Architecture of Skeletal Muscle in Isometric and Dynamic Contractions. Ettema GJC, PhD diss., Vrije Universiteit, Amsterdam, 1990.

[305] EMGGEN: A Software Package for Myoelectric Signal Generation

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Sponsor: *NeuroMuscular Research Center; Politecnico di Torino; Liberty Mutual Insurance Company*

Purpose—We have implemented a computer model to investigate the relationships between the myoelectric signal generation mechanisms and their spectral and amplitude parameters. The modular software package may be used to study different techniques for estimating the average muscle fiber conduction velocity, and to synthesize test signals to allow objective evaluation of the accuracy of myoelectric signal decomposition algorithms.

Methodology—The package, EMGGEN, is based on an extended version of the Lindstrom's model. It allows the user to synthesize either surface or internal myoelectric signals, simulating voluntary or electrically elicited contractions. Both monopolar and bipolar electrodes may be simulated, as well as single differential and double differential signals.

EMGGEN consists of two sections. The first allows the user to build the myoelectric signal interactively by choosing the number of active motor units, as well as

the depth and distance between the electrode location and the innervation zone, the initial conduction velocity and its variations during the contraction, the firing rate, and the inter-pulse interval variability for each unit. During the interactive section, the user can verify the effect of each choice in both frequency and time domain by means of graphics and numerical values. At the end of the interactive section, a report file automatically summarizes the characteristics of the signal to be generated. The second section generates the signal starting from the data that was interactively entered by the user. The user interface has been designed to be as friendly as possible. A detailed manual describing EMGGEN is available. Program EMGGEN runs under the VAX/VMS operating system.

Future Plans/Implications—A more powerful version of the program, specifically oriented to computer-aided instruction, will soon be available for IBM-AT or 386-based machines.

[306] Portable 8-Channel Myoelectric Preamplifier

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Sponsor: *NeuroMuscular Research Center*

Purpose—An increased number of investigations conducted at the NeuroMuscular Research Center (NMRC) have created the need for a preamplifier that is both portable and capable of processing simultaneous multiple myoelectric signals. The NMRC Design Laboratory has developed an 8-channel preamplifier to address this need. The system consists of an 8-channel belt-mounted preamplifier module, 50-foot umbilical cable, and power supply

box. It is used in conjunction with our improved "standard" electrodes, making it fully compatible with the muscle fatigue monitor (MFM) systems and equipment.

Methodology/Progress—The preamplifier is produced on a custom-printed circuit board and designed to provide subject safety by incorporating total galvanic isolation between the standard surface electrodes and signal

processing instrumentation. Other design features include variable gain and channel select function, and bandpass filters to remove frequency components of signals that are outside the range of interest.

Application for the preamplifier system include gait analysis, remote workstation testing, and automobile studies. Three units have been built and are currently in use in several investigations.

[307] EMG Evaluation of Car Seats Associated with Fatigue and Muscle Activity

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Sponsor: *Nissan Research & Development, Inc.*

Purpose—A collaborative study between the NMRC and the Massachusetts Institute of Technology (MIT) was recently supported by the Nissan Motor Company to develop new criteria for evaluating automobile seating. A pilot study was conducted to demonstrate the feasibility of using a surface electromyographic (EMG) array of electrodes to monitor muscle fatigue during prolonged periods of highway driving. Pilot studies by the Department of Mechanical Engineering at MIT were also conducted. MIT developed and tested a multidimensional scaling technique to analyze psychometric components of fatigue associated with driving. The EMG and multidimensional scaling techniques are combined in the present study with concurrent measurements of body motion using a three-dimensional position sensor.

Methodology—The measurement system is presently being used to analyze five different car seats provided by the engineering staff of Nissan Motor Company. Five

subjects will be tested for each of the seats, which include a standard production seat and four prototype seats, each with very different design features. The seats are being tested under actual driving conditions over a 4-hour test period. Nine muscle sites from the neck, shoulders, upper and lower back, and right lower limb are monitored by the EMG array. Repeat tests have been incorporated into the protocol to assess the reproducibility of results on different days and in different subjects.

Following completion of data collection, EMG spectral parameters and amplitude parameters will be averaged across subjects and compared for each seat. Physiologic and psychometric fatigue indices will be correlated to body movement and muscle activity to identify which car seat designs limit fatigue during driving.

Implications—If successful, procedures developed for this study may be applied to assess other design factors of the automobile interior that reduce fatigue and thereby improve the safety and comfort of the driver.

[308] EMG Power Spectrum and Histological Analysis: Percutaneous Biopsies

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Sponsor: *Ontario Ministry of Health, Physicians' Services, Inc. Foundation*

Purpose—In order to investigate the hypothesis, based on electromyogram (EMG) power spectrum investigations, that some patients displayed an EMG profile which is indicative of a deficient endurance capacity in the multifidus muscle, a study was initiated to collect muscle specimens for histological analysis. The study involved the use of the Stille-Eriksson biopsy needle which has

been recommended for tissue sampling of the erector spinae muscles.

Progress—Explorative investigations with the Stille-Eriksson needle on patients who were seen for surgery led us to question the clinical usefulness of the needle. Changes on the needle failed to improve its performance

sufficiently for reliable histochemical analysis. Based on these observations, it was decided that a direct incisional biopsy technique offers a safer and less traumatic way of obtaining suitable muscle specimens from superficial paraspinal muscles.

Implications—Studies are required to examine the validity of proposed relationships between EMG parameters

of the power spectrum and the actual histochemical composition of the muscle. This investigation should be useful in identifying clinically appropriate muscle specimen collection procedures.

Recent Publications Resulting from This Research

✓Percutaneous Biopsies with the Stille-Eriksson Needle. Biedermann HJ, Shoemaker PJ, *Internat J Sports Med* 11(2):168, 1990.

[309] Temporomandibular Joint Pain Syndrome: EMG Power Spectrum Analysis of the Masseter and Temporalis Muscles Before and After Occlusal Splint Therapy

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Sponsor: Ontario Ministry of Health, Physicians' Services Inc. Foundation

Purpose—Current dental treatment interventions for chronic temporomandibular joint syndrome (TMJS) are predominantly based on neuromuscular theories that implicate hyperactivity of the masticatory muscles due to dental malocclusion, leading to muscle fatigue and, consequently, pain. The treatment rationale is to reduce tension levels in the masticatory muscles by correcting dental malocclusion, usually by occlusal splinting. A major problem with this theoretical approach is that the expected post-treatment reductions in masticatory muscle EMG levels have not always been found, and where they have occurred, they have not been correlated with subjective and clinical signs of improvement.

We suggest that TMJS treatment studies employing EMG amplitude measures may have failed to find changes consistent with clinical outcomes because such measures provide inadequate information, permitting only a limited insight into the functional characteristics of the masticatory muscles (i.e., degree of tension/relaxation). Rather than resulting from a simple reduction in muscle tension level, clinical improvement in TMJ pain patients treated by the above methods may, in fact, be due to a reduction in *fatiguability* due to muscle adaptation to changes in functional demand.

If this hypothesis is correct, EMG power spectrum analysis, not rectified mean squares (RMS) comparison, is the appropriate outcome measure in the study of TMJS. Power spectrum analysis offers information regarding both muscle function and corresponding morphological characteristics (i.e., muscle fatigue and

recovery, fiber-typing, fiber type recruitment patterns) that would not be reflected in measures limited to amplitude of the EMG signal.

A number of investigators have examined power spectrum characteristics of the masticatory muscles under conditions of fatigue in symptom-free normal subjects. These studies have consistently shown a shift in the EMG power spectrum of the masseter and anterior temporalis muscles to lower mean frequencies during maximal or submaximal voluntary clenching indicating metabolic fatigue in the muscle. To date, however, power spectrum investigations of masticatory muscle fatigue have been limited to normal subjects.

Progress—We have recently initiated a study that will evaluate both EMG power spectrum and RMS parameters in TMJ pain patients undergoing occlusal splint therapy. Because power spectrum recording technique relies on surface electrodes, and because the frequency parameter changes are related to changes in the conduction velocity of the muscle fibers, the proper placement of surface electrodes with respect to muscle fiber direction is essential in order to obtain parameters that can be interpreted with respect to the histochemical structure of the muscle under investigation. So far, placement of the electrodes in power spectrum investigations of the masseter and temporalis muscles has been determined by muscle palpation and reference to external anatomical landmarks. The validity of these external criteria, however, in identifying accurately the anatomical direction of the underlying muscle fibers,

has yet to be demonstrated. A preliminary cadaveric study was therefore necessary to address this concern.

Results—A cadaveric study revealed a number of surface landmarks, easily palpable through the skin, that can be used reliably to identify the direction of masseter and

temporalis muscle fibers, and to guide the placement of surface electrodes.

Implications—Given these findings, reliable EMG power spectrum investigations of the masseter and temporalis muscles can now be undertaken.

B. Ligaments and Tendons

[310] Laser Biostimulation of Healing Tendons: Effects of Treatment Parameters

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Sponsor: VA Rehabilitation Research and Development Service (Project #A534-RA)

Purpose—Experimental observation of developing collagen fibrils in membrane-bound intracytoplasmic vesicles is a baffling phenomenon which contradicts the biochemical dogma that polymerization of pro-collagen molecules into collagen fibrils occur extracellularly with native periodicity. However, because this phenomenon is commonly observed in collagen-producing cells exposed to antitubulin agents, anabolic steroids, and disease processes, it is acknowledged as an evidence of rapid collagen turnover. Since laser photostimulation has been shown to modulate collagen synthesis, the ultrastructure of regenerating tendons exposed to a low intensity Ga-As laser beam was studied: 1) to determine if laser treatment induces the presence of vacuolar fibrils; and, 2) to describe the ultrastructure of laser photostimulated tendon fibroblasts.

Methodology/Progress—The right calcaneal tendons of nine rabbits were surgically tenotomized, repaired, and immobilized in plaster. Beginning from the first day after surgery, the tenotomized tendons of six rabbits were exposed to a Ga-As laser beam of 904 nm wavelength and 7 mW average power. The beam was applied transcutaneously every day, pulsed 2,336 times per second, and both treatment duration and irradiation area varied to yield an energy density of either 4 J cm^{-2} (three rabbits) or 5 J cm^{-2} (three rabbits). The tenotomized tendons of the

remaining three rabbits were not exposed to a laser beam; thus, these tendons served as tenotomized nontreated controls. The right calcaneal tendons of three other rabbits served as normal intact nontenotomized controls. On the fourteenth postoperative day, neotendons were surgically excised from the site of tenotomy of each tendon, processed for electron microscopy, then visualized and photographed under a Philips 300 or a JOEL 100CX electron microscope. Vacuolar fibrils were observed exclusively in the fibroblasts of laser photostimulated tendons. The vacuolar fibrils had the same spatial orientation as those matrical fibrils within their immediate vicinity. Thus, in transverse, oblique, and longitudinal sections, matrical and vacuolar fibrils were correspondingly transverse, oblique, or longitudinal in appearance. Longitudinal sections revealed that vacuolar fibrils had the characteristic banding pattern of collagen, as did matrical fibrils. No other ultrastructural differences were observed between laser-treated tendons and tenotomized nontreated controls. In line with previous reports, sections of the regenerating tendon were remarkably different from those of intact nontenotomized tendons.

Implications—These findings suggest that exposure to laser beam promotes rapid collagen turnover in regenerating rabbit calcaneal tendons.

[311] Treatment of Variable Partial Flexor Tendon Lacerations

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Sponsor: VA Rehabilitation Research and Development Service (Project #A505-RA)

Purpose—Penetrating trauma to the hand often produces partial lacerations of the digital flexor tendons. While primary surgical repair of complete flexor tendon lacerations has been generally accepted, the role for tenorrhaphy in the management of incomplete tendon injuries has remained controversial. The goal of this project was to develop a controlled animal model of partial flexor tendon injuries. The model was then to be used in studying the effects of different repair techniques on the healing of partial tendon lacerations.

Methodology—In preliminary investigations, we developed an instrument we called the "tenotome" which allowed us to produce very consistent partial tendon lacerations. The tenotome was used to produce accurate 75% lacerations of the flexor profundus tendons of 220 adult female chickens. The animals were randomized to groups studying: 1) unrepaired tendons; 2) epitendinous repairs with 7-0 Prolene; or, 3) modified Kessler repairs with a 5-0 core suture and a 7-0 epitendinous stitch. In a fourth group, the tendons were exposed, but not lacerated, to serve as a control. All of the chickens were placed postoperatively in rubber-band splints, allowing immediate constrained digital motion while protecting the tendon repairs. At intervals of 0 to 60 days, the animals were killed with an overdose of IV KCl, and the tendons were harvested for biomechanical testing of tendon repair strength and tendon gliding.

Results—The rupture strengths immediately postrepair (day 0) averaged 53.96 N for the unrepaired group; 54.15 N for the epitendinous repairs; and 56.80 N for the modified Kessler group. The unrepaired tendons and the epitendinous repairs showed modest insignificant losses in repair strength at 10 and 20 days, with gains in strength at the 40- and 60-day intervals. There were no significant differences in strength between the unrepaired tendons and epitendinous repairs at any time interval. In contrast, the lacerations repaired with a modified Kessler suture

showed significant losses in repair strength at the 10- and 20-day intervals, with failure to return to baseline strength by 60 days. The tendons repaired with a modified Kessler suture were significantly weaker than the other groups at all intervals after day 0 ($p < 0.05$). There were 6 *in vivo* tendon ruptures among the 30 tendons repaired with a modified Kessler stitch, while the unrepaired tendons and the epitendinous group had only a single tendon rupture each.

The modified Kessler repairs also showed increased edema and adhesions around the repair site when compared to unrepaired tendons or those with epitendinous repairs. The subjective observation of increased adhesions was confirmed with objective tests of tendon gliding. Partial lacerations which had not been sutured, or sutured with epitendinous stitches only, showed nearly normal flexion of the DIP joints distal to the repair site. In contrast, the modified Kessler repairs showed severely restricted DIP joint flexion due to dense adhesions around the repair site.

Implications—Partial tendon lacerations can be repaired with epitendinous sutures without producing the adverse effects seen with placement of large core sutures in the modified Kessler technique. Judicious clinical use of epitendinous sutures to repair loose tendon flaps should help minimize the mechanical complications of tendon triggering, entrapment of tendon flaps, late rupture, and adhesion formation.

The animal model and techniques developed in this study should prove very useful in future studies of flexor tendon healing.

Recent Publications Resulting from This Research

The Effect of Different Repair Techniques on the Strength of Partial Flexor Tendon Lacerations Over Time. Hitchcock TF et al., Abstracts of the 35th Annual Meeting of the Orthopaedic Research Society, 14:275, 1989.

New Technique for Producing Uniform Partial Lacerations of Tendons. Hitchcock TF et al., J Orthop Res 7(3):451-455, 1989.

[312] Structural and Functional Properties of Normal and Healing Ligaments: Part 1

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Sponsor: VA Rehabilitation Research and Development Service (Project #A188-3RA)

Purpose—We have developed a new injury model to study medial collateral ligament (MCL) healing in the rabbit. Although many experimental animal models have been used to examine MCL healing, few have included a concomitant injury to the ligament in sections to bone as observed clinically. Using a combined injury model, long-term healing was evaluated following conservative treatment or primary repair of the MCL.

Methodology—In both groups (repaired and nonrepaired), the left MCL of each animal was surgically exposed, and a 2.5 mm diameter stainless steel rod was passed transversely beneath the ligament at the joint line. A small notch was made on each side of the MCL at the level of the rod. The ligament was ruptured in tension by pulling on the rod, creating a “mop-end” midsubstance tear. In half of the animals, the torn ligament ends were surgically repaired, while those of the remaining animals were manually approximated. At 6, 12, and 52 weeks postoperatively, one-third of the animals in each group (repaired and nonrepaired) were sacrificed, and healing of the MCL was evaluated by comparing the varus-valgus (V-V) knee rotation, the structural properties of the femur-MCL-tibia complex (FMTC) and the mechanical properties of the MCL substance.

Results—No significant differences were seen in the V-V rotations or the tensile properties between the repaired and nonrepaired groups at either 6, 12, or 52 weeks, suggesting that in a model that combines MCL substance and insertion site injury, surgical repair of the MCL and conservative treatment yield similar results. At both 6 and 12 weeks, the V-V rotations of the repaired and nonrepaired knee and structural properties of the repaired and nonrepaired FMTCs (ultimate load, ultimate deformation, energy absorbed, and stiffness) were significantly different from those of the contralateral sham-operated knees ($P < 0.01$ in all cases). However, by 52 weeks, the V-V knee rotation and linear stiffness of the experimental FMTCs were not significantly different from the sham values ($P > 0.1$ in all cases). There was a significant effect of healing time ($p < 0.01$) on these properties. At 12 and

52 weeks postoperatively, all experimental specimens failed in the ligament substance, and the tensile strength and ultimate strain of both the repaired and nonrepaired specimens were significantly less than that of the shams ($p < 0.01$ in all cases).

Future Plans/Implications—The rates of recovery between the ligament substance and the insertion sites were found to be asynchronous as there was a progressive change in failure mode from tibial avulsion at 6 weeks to mid-substance at 52 weeks. The strength of the tibial insertion site increased during the time course of healing while the ligament substance showed little change after the first 12 weeks. A lack of complete recovery of the mechanical properties of the MCL was observed. However, increases in MCL cross-sectional area helped the FMTC to achieve structural properties near to those of the sham control. This suggests that this is a useful model of clinical injury and, therefore, is suitable for the long-term study of grade III MCL injury.

Recent Publications Resulting from This Research

- An Analytical Technique for Defining the Mechanical Properties of Ligament Tissues. Gomez MA, Kwan MK, Woo SL-Y, Joint Biomechanics Symposium at the 3rd Joint ASCE/ASME Mechanics Conference, San Diego, 45-48, 1989.
- Comparison of the Mechanical Properties of the Medial Collateral and Anterior Cruciate Ligaments of the Rabbit Knee. Newton PO et al., Joint Biomechanics Symposium at the 3rd Joint ASCE/ASME Mechanics Conference, San Diego, 53-56, 1989.
- Comparison of Three Methods for Measuring the Cross-Sectional Area Along the Rabbit Medial Collateral Ligament. Danto MI et al., Joint Biomechanics Symposium at the 3rd Joint ASCE/ASME Mechanics Conference, San Diego, 97-100, 1989.
- Effect of Partial and Total Transection of the Anterior Cruciate Ligament on Medial Collateral Ligament Healing in the Canine Knee. Ohland KJ et al., in Transactions of the 35th Annual Orthopedic Research Society, 14:322, 1989.
- The Effects of Age and Sex on the Biomechanical Properties of the Medial Collateral Ligament. Ohland KJ et al., in Transactions of the ASME Winter Annual Meeting, San Francisco, BED 15:113-114, 1989.
- Medial Collateral Ligament Healing Subsequent to Different Treatment Regimens. Gomez MA et al., J Appl Physiol 66(1):245-252, 1989.
- A Structural Model to Describe the Stress-Strain Behavior for Parallel-Fibered Collagenous Tissues. Kwan MK, Woo SL-Y,

- Transactions of the ASME Winter Annual Meeting, San Francisco, BED 15:91-92, 1989.
- The Effects of Strain Rate on the Properties of the Medial Collateral Ligaments in Skeletally Immature and Skeletally Mature Rabbits: A Biomechanical and Histological Study. Woo SL-Y et al., *J Orthop Res* 8:712-721, 1990.
- Effects of Surgical Treatment and Immobilization on the Healing of the Medial Collateral Ligament: A Long-Term Multidisciplinary Study. Inoue M et al., *Conn Tiss Res* 20:1-14, 1990.
- The Effects of Transection of the Anterior Cruciate Ligament on Healing of the Medial Collateral Ligament: A Biomechanical Study of the Knee in Dogs. Woo SL-Y et al., *J Bone Joint Surg* 72A:382-392, 1990.
- Improved Methodologies to Differentiate the Mechanical Properties of the Rabbit Anterior Cruciate Ligament (ACL) and Medial Collateral Ligament (MCL). Newton PO et al., in Transactions of the 36th Annual Orthopedic Research Society, 16:509, 1990.
- Long-Term Healing of the Femur-Medial Collateral Ligament-Tibia Complex (FMTC). Weiss JA et al., in Transactions of the First World Congress of Biomechanics, La Jolla, CA, II:292, 1990.
- Long-Term Healing of the Medial Collateral Ligament (MCL) and Its Insertion Sites. Ohland KJ et al., in Transactions of the 37th Annual Orthopedic Research Society, 16, 1990.
- Measurement of Changes in Ligament Tension with Knee Motion and Skeletal Maturation. Woo SL-Y et al., *J Biomech Eng* 112:46-51, 1990.
- A New Injury Model to Study Medial Collateral Ligament Healing. Weiss JA et al., in Transactions of the 36th Annual Orthopedic Research Society 15:60, 1990.
- Quantitative Morphology of the Anterior Cruciate and Medial Collateral Ligaments. Hart RA, Newton PO, Woo SL-Y, in Transactions of the 37th Annual Orthopedic Research Society, 16, 1990.
- Aging and Sex Related Changes in the Biomechanical Properties of the Rabbit Medial Collateral Ligament. Woo SL-Y, Ohland KJ, Weiss JA, *Mech Aging Dev* (accepted for publication).
- The Effects of Increased Tension on Healing and Normal Collateral Ligaments. Gomez MA et al., *Am J Sports Med* (accepted for publication).
- The Use of a Laser Micrometer System to Determine the Cross-Sectional Shape and Area of Ligaments: A Comparative Study with Two Existing Methods. Woo SL-Y et al., *J Biomech Eng* (accepted for publication).

Award

The American Orthopedic Society for Sports Medicine 1990
O'Donoghue Sports Injury Research Award.

[312a] Structural and Functional Properties of Normal and Healing Ligaments: Part 2

Purpose—Complete disruption of the medial collateral ligament (MCL) often occurs together with the rupture of the anterior cruciate ligament (ACL) and damage to the medial meniscus—the so called “triad” injury. Using our recently developed model for MCL injury, which included damage of the MCL substance as well as its insertions to bone, we examined MCL healing following a triad injury.

Methodology—In all animals, the MCL was ruptured at the joint line by pulling medially on a 2.5 mm diameter rod passed beneath the ligament. In half the animals, the ACL was then surgically transected and the inner rim ($\cong 50\%$) of the medial meniscus was excised. At 6 and 12 weeks postoperatively, half the animals in each group (isolated MCL rupture and triad injury) were sacrificed, and healing of the MCL was evaluated by comparing the V-V knee rotation, the structural properties of the femur-MCL-tibia complex (FMTC) and the mechanical properties of the MCL substance. The V-V knee rotations of an additional six knees were measured intact and successively following isolated MCL rupture and triad injury.

Results—The animals with a triad injury experienced substantial joint degeneration by 6 weeks. V-V rotations were nearly three times higher for the triad injured knees than for those with isolated MCL rupture ($P < 0.001$) and

remained elevated with time. The ultimate load of the FMTCs of the triad injured knees improved with time ($P < 0.05$), but were only 55% of those with isolated MCL rupture ($P < 0.05$). The modulus of the healing tissue from the triad injured knees was less than half of that of the tissue from the isolated MCL ruptured knees ($P < 0.05$).

Future Plans/Implications—This study demonstrates the deleterious effects of an untreated triad injury on the healing potential of the MCL substance and its insertions. The biomechanical properties of the FMTC and MCL substance imply that the MCL forms a much larger structure following triad injury in an attempt to compensate for its inferior mechanical properties. We have additionally found that after ACL reconstruction, the V-V rotation of the triad injured knees could be restored suggesting that the healing of the MCL may be enhanced by restoring ACL function. We plan to evaluate MCL healing at 6, 12 and 52 weeks following triad injury with ACL reconstruction.

Location Change—The research described herein was performed at the VA Medical Center, San Diego, CA. Dr. Woo transferred to the VA Medical Center, University Drive C, Pittsburgh, PA effective October 1, 1990.

[313] Anterior Cruciate Ligament Healing

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Sponsor: National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health

Purpose—Interstitial tears of the anterior cruciate ligament (ACL) do not heal. Studies have focused on the fundamental biological explanation for this deficit. Results with a partial laceration model suggest that simple biomechanical explanations and postulating a “hostile environment” in the synovium are not sufficient to explain the observed healing deficiency. On the basis of original observations, it is proposed that the fibroblast of the ACL is a transitional cell with morphological features similar to the fibrocartilage cell of the meniscus. Ultrastructural studies and immunocytochemical studies with monoclonal antibodies (Mabs) against fibronectin (Fn) show striking differences between the cells of the ACL and the medial collateral ligament (MCL). The ACL lacks the long cytoplasmic processes seen in the MCL and in most other fibrous connective tissue; instead, ACL cells rest in a lacuna-like pool of undifferentiated matrices and partially resemble cartilage cells. It is believed that this morphological appearance may be predictive of the functional response of these cells to injury.

Methodology—A multidisciplinary approach will be used to evaluate and compare the ACL and MCL. State-of-the-art mechanical testing will determine material properties. Molecular and biochemical procedures will assess the metabolic state of these tissues. Scanning electron microscope (EM) studies will be used to define the ligament ultrastructure.

Progress/Results—In a model system of ligament injury, gross healing was defined as complete bridging of the laceration. At the 3- and 7-day time periods, five of the six MCLs were healed; the defect was filled with a translucent “membrane.” By 14 days, all lacerations in the MCLs (3/3) were covered by a more hypertrophic ligamentous-like tissue, which seemed to only slightly increase by 28 days.

With the exception of one bridged laceration at 14 days, the lacerations in the ACLs did not heal. The sharp edges created at the time of surgery were rounded off.

Results demonstrate that procollagen messenger (mRNA) levels in MCL tissue are higher than ACL under normal conditions, and increase in response to injury.

The differences in the procollagen mRNA levels of MCL and ACL may reflect the synthesis of collagen in these tissues, and may contribute to differences in their healing capacities.

The stress-strain relationship of each ligament was determined. To achieve a uniform stress distribution during uniaxial tensile testing, the ACL was divided into medial and lateral portions. The mechanical properties of these two portions of the ACL were found to be identical. However, the tangent modulus for the ACL (420 ± 70 MPa) was nearly 50% that of the MCL (810 ± 70 MPa), indicating that the MCL is composed of an intrinsically stiffer material. The tensile strength of the MCL was nearly twice that of the ACL. The strain at failure was similar for the two ligaments. Scanning EM studies showed that the ACL was composed of collagen fascicles with a large amount of endotenon between fascicles. The collagen fibers of the MCL were arranged much more compactly without prominent fascicular divisions.

Future Plans/Implications—The current models and approaches will be extended to provide more detailed information. Hyaluronan and growth factors (including those known to be successful in skin wound healing) will be incorporated to modify the healing response. It is encouraging that recent studies show meniscus healing to be facilitated by fibrin clot, which contains a variety of growth factors able to stimulate chemotaxis, mitogenesis, and/or protein synthesis. Some of this work will be accomplished in cell culture explants from rabbit knee ligament studies.

Recent Publications Resulting from This Research

- Early Histologic, Metabolic, and Vascular Assessment of Anterior Cruciate Ligament Autografts. Kleiner JB et al., *J Orthop Res* 7(2):235-242, 1989.
- Medial Collateral Ligament Healing Subsequent to Different Treatment Regimens. Gomez MA et al., *J Appl Physiol* 66(1):245-252, 1989.
- The Early Effect of High Molecular Weight Hyaluronan (Hyaluronic Acid) on Anterior Cruciate Ligament Healing: An Experimental Study in Rabbits. Wiig ME et al., *J Orthop Res* 8(3):425-434, 1990.
- Quantitative Assessment by Competitive ELISA of Fibronectin (Fn) in Tendons and Ligaments. Amiel D et al., *Matrix* 9(6):421-427, 1990.

IX. Neurological and Vascular Disorders

For additional information on topics related to this category see the following Progress Reports: [39], [99], [110], [111], [163], [174], [180], [192], [261], [406], [407], [408], [409], [451], [567].

A. General

[314] Comparison of Treatment Programs for Multiple Sclerosis Rehabilitation

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Sponsor: VA Rehabilitation Research and Development Service (Project #B395-RA)

Purpose—The goal of this project is to examine the effectiveness of interdisciplinary team care compared with standard neurological care for patients with multiple sclerosis (MS). Our main hypothesis is that coordinated care by experienced practitioners will maximize patients' quality of life, and may eliminate preventable complications of MS.

Methodology—Patients with definite or probable MS are evaluated at baseline, 6, and 12 months. Study measures include the Minimal Record of Disability for Multiple Sclerosis (MRD), the Sickness Impact Profile (SIP), patient satisfaction with health care, the Campbell Index of Life Satisfaction, and enumeration of VA and non-VA medical expenditures. Patients at the Portland VA Medical Center will continue to receive comprehensive neurological care. Patients at the Denver VA Medical Center will be treated in an interdisciplinary team clinic, managed by a nurse practitioner case manager. The team carries out a comprehensive evaluation of the patient's physical, psychological, and social status. Realistic care and rehabilitation goals are established, and the nurse practitioner ensures that the plans are effectively carried out.

Progress—A total of 163 patients participated in the study (82 at Denver and 81 at Portland). Thus far, 116 patients completed 6 months of follow-up, and 32 patients completed 12 months of follow-up. The patients were

88% male, with an average age of 49 years. Most (67%) had chronic progressive MS with an average duration of 17.7 years. The average Expanded Disability Status Scale (EDSS) scores were 6.1. Overall, the Portland patients have a slightly more severe degree of MS than do the Denver patients (EDSS 5.9 in Denver and 6.3 in Portland, $p=0.20$). The groups are otherwise quite comparable in the type, duration, and severity of their MS.

Preliminary Results—We found that the patients had 94 total hospitalizations, including 72 directly related to MS. Of the MS-related hospitalizations, 18 were due to potentially preventable problems. The majority of these hospitalizations were due to urinary tract infections with an estimated total cost of \$186,000. This high frequency of preventable hospitalizations points to an area where an interdisciplinary team focused on aggressive rehabilitation of MS patients can have a major functional and cost impact.

We also examined the problem of caregiver burden and found that 49% of patients had a nonprofessional caregiver (24) working with them for an average of 10 years, and spending an average of 43 hours per week in direct care. Since only 15% of our patients are employed, and only 43% of their caregivers are employed, the economic impact of MS on the family unit is considerable. The caregivers had a very high degree of burden, and this correlated especially with psychosocial dysfunction in the patients.

Our preliminary analysis shows a positive effect of the interdisciplinary team on functional outcomes and satisfaction with health care. At 6 months, the average EDDS score declined from 6.08 to 6.28 with no significant difference between Portland and Denver. Examining functional issues, we found that at 6 months, Denver patients fared significantly better than Portland patients. Functional status, as measured by total Incapacity Status Score (ISS), was better in Denver than Portland, even after adjusting for baseline differences (ISS mean scores 20.2 in Denver, 28.9 in Portland, $F=4.95$, $p=0.028$). In 10 of the 16 subscales of the ISS, the Denver group either improved or showed less decline than did the Portland group. Patient satisfaction with health care improved in Denver ($p<0.001$) and declined in Portland ($p=0.041$). These findings give strong support to the concept that an

interdisciplinary team can result in important improvement in MS patient functional status and that further testing of this concept is warranted.

Recent Publications Resulting from This Research

- A Nurse-Managed Multiple Sclerosis Clinic: Improved Quality of Life for Persons with MS. Winters S et al., *Rehabil Nurs* 14(1):13-22, 1989.
- The Team Approach: Two Models for MS Rehabilitation. Burks JS, Gellerman E, Licari P, *Paraplegia News* 43(4):28-30, 1989.
- Care-Giver Burden in Multiple Sclerosis. Prochazka AV, Mitchell W, Licari P, *Clin Res* 38:107A, 1990.
- Health Care Costs of Multiple Sclerosis. Bourdette DN et al., *Neurology (Suppl 1)*40:276, 1990.
- Bladder, Bowel and Sexual Dysfunction in Multiple Sclerosis. Bourdette DN, in *Multiple Sclerosis: Current Status of Research and Treatment*, R.M. Herndon, F.J. Seil (Eds.). New York: Demos Publications (in press).

[315] Neuromuscular Function: Comparison of Symptomatic and Asymptomatic Postpolio Subjects

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Sponsor: *Easter Seal Research Foundation*

Purpose—Our research was designed to compare symptomatic to asymptomatic postpolio individuals to determine if there were differences in muscle strength, endurance, work capacity, perception of exertion during activity, manner in which the muscle compensates for fatigue, or ability of the muscle to recover strength after activity.

Methodology—We studied quadriceps femoris function in 91 individuals: 41 control, 34 symptomatic and 16 asymptomatic postpolio subjects. Isometric muscle strength was measured in the quadriceps muscles. Endurance testing was performed at 40% of maximal volitional contraction (MVC) until the subject was no longer able to maintain the required torque. Work capacity was defined as the product of torque and endurance time. Rating of perceived exertion was determined at regular intervals during the endurance test. Surface electrophysiologic measures (median frequency of the power spectrum, root mean squared EMG) were made to determine the pattern of muscle fatigue. Post-endurance strength testing was also performed at regular intervals for 10 minutes after exhaustion. Following the above testing, quantitative EMG testing of the quadriceps femoris muscle was performed.

Results/Implications—Quantitative EMG demonstrated that the symptomatic postpolio group had evidence of more severe acute poliomyelitis than in the asymptomatic group. Isometric peak torque of the quadriceps was least in the symptomatic group and greatest in the control group. The endurance time was not statistically different among the three groups, although the isometric work capacity was significantly less in the symptomatic group than the other two groups. Rating of perceived exertion and electrophysiologic measures were the same in all three groups during activity. The symptomatic subjects, however, recovered their strength less readily than did control subjects while the asymptomatic subjects recovered their strength in similar fashion to control subjects.

We also studied the effect of pacing (use of intermittent activity) in seven symptomatic postpolio subjects. In this study, the subjects were tested on three separate days at least one week apart. On the first day (constant exercise) the subject performed the strength and endurance testing as described above. On the second test day (quartile study) the subject performed the same isometric work as on the first test day at 40% of MVC, but the isometric exercise was divided into quartiles with 2-minute rest breaks between quartiles. On the third test day (interval exercise) the subject performed 20-second

intervals of isometric exercise at 40% of MVC until either the rating of perceived exertion was greater than 17 (very hard) or 18 intervals of isometric work were performed.

The results of this study demonstrated significantly less evidence of muscle fatigue by rating of perceived exertion as well as by the electrophysiologic measures in both the quartile and the interval studies as compared to the constant exercise study. The relative recovery of strength at 30 seconds after activity was also significantly greater in quartile and interval exercise than for constant exercise. The amount of isometric exercise performed during the interval exercise paradigm was 237% greater than that performed during constant exercise. Thus, symptomatic postpolio subjects were able to perform similar or greater isometric exercise with less evidence of local muscle fatigue by pacing their activity. This evidence highly supports the concept that pacing of activity can be very beneficial in symptomatic postpolio individuals.

Recent Publications Resulting from This Research

- Symptoms and Clinical Impressions of Patients Seen in a Postpolio Clinic. Agre JC, Rodriquez AA, Sperling KB, Arch Phys Med Rehabil 70:367-370, 1989.
- Neuromuscular Function: Comparison of Symptomatic and Asymptomatic Polio Subjects to Control Subjects. Agre JC, Rodriquez AA, Arch Phys Med Rehabil 71:545-551, 1990.
- Correlation of Quantitative Motor Unit Action Potentials with Neuromuscular Variables and Surface Electromyographic Power Spectrum Characteristics in Polio Survivors and Controls. Rodriquez AA, Agre JC, Muscle Nerve (in press).
- Electrophysiologic Study of the Quadriceps Muscles During Fatiguing Exercise and Recovery: A Comparison of Symptomatic Polios to Asymptomatic Polios and Controls. Rodriquez AA, Agre JC, Arch Phys Med Rehabil (in press).
- Neuromuscular Function Remains Stable in Symptomatic and Asymptomatic Polio Survivors at One Year Follow-up. Agre JC, Rodriquez AA, Arch Phys Med Rehabil (in press).
- Rating of Perceived Exertion and Fatigue During Isometric Exercise in Postpolio Subjects. Rodriquez AA, Agre JC, Arch Phys Med Rehabil (in press).

[316] Mechanisms of Damage-Induced Trigeminal Reorganization

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Sponsor: National Institute of Dental Research, National Institutes of Health

Purpose—This research will define the peripheral and central sequelae of trigeminal nerve damage and, in addition, determine whether these consequences can be altered by treatment with neuronal growth promoters such as bovine brain gangliosides. The study is composed of six projects, each of which will examine an aspect of the reorganization which follows transection of the infra-orbital nerve in either adult or neonatal rats.

Project 1 will employ electron microscopic, multiple retrograde tracing, and electrophysiological methods to address issues of ganglion cell survival and reorganization of peripheral connectivity.

Project 2 will use transganglionic tracing and injection of individual, functionally characterized, primary afferents with horseradish peroxidase (HRP) to determine the extent to which nerve damage or inactivation alters the primary afferent innervation of the trigeminal brainstem complex and whether changes in the central arbors of individual axons can be correlated with alterations in their peripheral connectivity.

Project 3 will concentrate on potential changes in the brainstem organization. In these experiments, novel

morphometric techniques will be employed to delineate the effects of both deafferentation and removal of targets upon the survival of trigeminal brainstem neurons.

Project 4 will employ retrograde tracing, electrophysiological, and HRP injection techniques to delineate the effects of nerve damage or inactivation upon the morphology, response properties, and projections of second order trigeminal neurons.

Project 5, like 4 and 3, will examine damage-induced changes in the organization of the trigeminal brainstem complex. In these experiments, however, the emphasis will be upon monaminergic pathways, which are well known to influence the responses of trigeminal neurons.

Project 6 will have as its focus studies concerned with the effects of treatment with bovine brain gangliosides upon neuronal survival and the events which surround and may influence axonal regeneration by surviving neurons. A parallel series of experiments will also examine the effects of gangliosides upon trigeminal ganglion cell survival and neuritogenesis *in vitro*.

[317] Microdialysis Membranes for Chronic Studies

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose/Methodology—During Phase I research of this project, microdialysis fibers were surface-modified to impart “biocompatible” surfaces (i.e., surfaces which were not neurotoxic and were not fouled by protein adsorption and cellular in-growth).

Results—*In vitro* testing of these fibers did not reveal any toxic effects on neurons or astrocytes. Although proteins did adsorb onto the membranes in these cultures, and some cellular infiltration was noted *in vitro*, occlusion of the membranes did not occur *in vitro*. In fact, the best surface-modified membranes, when implanted in striatum of rats, gave stable basal dopamine recoveries over a 13-day period. This is potentially a major breakthrough for chronic microdialysis given in previously-published results, and the widely-held belief that long-term implantation of dialysis membranes is not possible.

Future Plans—Phase II research will expand upon the results of Phase I. Three major sets of experiments are planned: 1) chronic monitoring of basal dopamine levels; 2) histological time course evaluation of the tissue changes around the dialysis fibers; and, 3) demonstration of end-use pharmacological testing. In addition, the production of second-generation probes, which will improve upon those currently available and broaden the scope of microdialysis applications, will be investigated.

Implications—The proposed research, on chronic microdialysis, surface modification, and biocompatibility, will greatly enhance the range of applications and utility of the microdialysis technique. Long-term neurophysiological and pharmacological studies will become possible. In addition, the inflammatory and foreign body responses caused by microdialysis fibers, which can distort findings even in acute experiments, will be avoided.

[318] Neural Pathways Involved in Tactile Discrimination

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—The proposed research is part of a project whose long-term goal is to add to our understanding of the tactile information processing capabilities and limitations of the somatosensory system, especially those neural regions and systems responsible for processing tactile information derived from mechanical stimulation of the glabrous surfaces of the hand.

Methodology—This project will examine the functional properties and stimulus-response relationships of single neurons of three spinal pathways which project, directly or indirectly, to the thalamic ventrobasal complex: the spinocervical tract, the postsynaptic dorsal column system, and the spinothalamic tract. Microelectrodes will be used to record extracellular activity of cell bodies or fibers in response to controlled mechanical stimulation of the glabrous skin of the raccoon's forepaw. Neurons will be identified as belonging to one of these three systems

by antidromic electrical stimulation of the appropriate region of spinal cord or brain stem.

Specific parameters to be examined include modality and adaptive properties, absolute thresholds, and receptive field areas, as well as effects of controlled mechanical stimulus velocity, displacement, and force on both dynamic and static discharge. Neurons will be sought which display properties suggesting excitatory or inhibitory convergences, and which display properties of feature detectors (e.g., preferential response to edges or laterally moving stimuli). Properties of neurons of the three spinal pathways will be compared with each other, as well as with properties of both primary afferents and neurons of the cuneate nucleus and thalamic ventrobasal complex, previously studied in this laboratory.

Implications—These studies should contribute to our knowledge of the differential contribution of three major

somatosensory pathways to the processing of tactile information acquired by a behaviorally salient tactile organ system, the forepaw or hand, especially its glabrous surfaces. This, in turn, should provide information relevant

to the design of devices for the utilization of tactile information by individuals handicapped in other sensory modalities. Findings should also have neurological relevance to the differential diagnosis of spinal cord injury or disease.

[319] Multi-Detector Brain Analysis System (MDBAS)

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The goal of this project is to develop, test, and validate the prototype of a new positron annihilation coincidence probe MultiProbe (formerly called the Positron Multi-Detector Brain Analysis System—PMDBAS). The MultiProbe includes significant new technology for: 1) MRI image registration; 2) low-cost time-of-flight resolution improvement; and, 3) improved computer-guided image region of interest (ROI) sampling.

Progress—The new MultiProbe technique can be applied to both positron tracers and with suitable alterations to single-photon emission computerized tomography (SPECT) tracers. The MultiProbe combines both image

mensuration of the size of the anatomical features, such as tumors, with measurement of their physiologic activity. It provides positron measurement capability at costs projected to be under 120% of positron emission tomography (PET) making it a viable supplement or replacement for PET in many types of studies.

It has application as a monitoring instrument necessary to observe tissue condition repeatedly over a long period of time. The system allows reduced radiation exposure and permits up to 50 fluorodeoxyglucose (FDG) scans per year versus a limit of 3 per year for PET. The design of the device also significantly reduces the time required to perform a single measurement.

[320] Cerebral Capillary Perfusion During Oxygen Lack

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Purpose—Cerebral oxygen delivery is controlled by both cerebral blood flow and the number of perfused capillaries. Control of the number of perfused cerebral capillaries, in contrast to cerebral blood flow, has not been extensively studied under oxygen supply-limited conditions. From our previous work, we know that only about half of the available cerebral capillaries are perfused at rest, and that this reserve can be utilized during oxygen supply stress. Both central and peripheral adrenergic neurons can alter cerebral oxygen delivery. Their influence on cerebral oxygen delivery appears more important under conditions of oxygen lack.

The primary hypothesis of this project is that central and peripheral noradrenergic neurons decrease cerebral oxygen delivery by reducing alterations in diffusion distance and cerebral blood flow during oxygen supply stress. We intend to study the effects of various means of

reducing oxygen supply (anemia, hypoxia, carbon monoxide, hypocapnia) on the perfusion of cerebral capillaries and sympathetic influence on the control of oxygen delivery in conscious rats. We also intend to study the relative importance of the cerebral capillary response to oxygen lack.

Methodology—To perform these studies, we have developed a method to determine perfused and total capillary density on a regional basis in conscious rat brain. A fluorescent dye is injected to reveal the perfused vessels. The tissue is then stained to reveal the total network. This method, when coupled with measurements of cerebral blood flow with iodoantipyrine, and cerebral oxygen extraction with microspectrophotometry, will give a complete picture of the cerebral response to oxygen supply changes. The importance of peripheral sympathetic

innervation, central noradrenergic neurons and the arterial chemoreceptors in the control of cerebral capillary perfusion under conditions of reduced oxygen supply will be assessed. This will be determined in experiments involving ablation of the cervical sympathetic ganglia and arterial chemoreceptors.

Future Plans/Implications—We will study the effects of blockade of central and peripheral adrenoceptors. The

importance of changes in intercapillary distance on tissue oxygenation will also be assessed through increases and decreases in cerebral capillary density. Cerebral oxygen supply can be controlled at both the arteriolar and capillary level. Through study of the influence of the sympathetic nervous system on these two levels of control, we hope to gain a better understanding of its normal control of cerebral oxygen supply.

[321] Time-Resolved Spectroscopy of Hemoglobin in the Brain

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The possibility of quantitative measurements of deoxyhemoglobin concentrations in the neonate and adult brain depends upon picosecond pulses of phase modulation spectroscopy that determine the optical path traveled by photons exiting the brain. Algorithms, based upon a program of milk and animal models, will be developed to permit localization of pathological states due to brain bleeding (i.e., hematomas or aneurysms). Thus, the possibility of nonradioactive, nonmagnetic, nonconfining studies based upon innocuous low-powered

deposition near red illumination on the surface of the head is the general goal of these studies.

Implications—These developments can lead to a new technology of quantitation and localization of normal and pathological levels of deoxyhemoglobin in the human brain. It is believed that this instrument has clinical applications and safety aspects that would allow it to be used wherever needed in research and clinical studies.

[322] Motor Control Systems in the Spinal Cord

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—This project was designed to provide information about the structure and function of neuronal mechanisms in the mammalian spinal cord which produce and control movement. These mechanisms include: reflex pathways that convey sensory information from primary afferents to alpha motoneurons; interactions between different reflex pathways; modulation of information flow through reflex pathways by supraspinal descending systems; and the production of autonomous rhythmic activity by central pattern generators within the spinal cord.

Methodology—Electrophysiological, neuroanatomical, and computer modeling approaches were used. Recent work has emphasized examination of the modulation of transmission through excitatory cutaneous reflex pathways by the spinal central pattern generator for locomotion, in order to clarify the organization of spinal interneurons that control the basic patterning of muscle activation during locomotion in the cat.

[323] Techniques for Making Connections with the Nervous and Musculoskeletal Systems

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—This project is intended to develop techniques and instrumentation for the acquisition and processing of neuroelectric signals from the central and peripheral nervous system in acute and chronic neurophysiological preparations. Because of this laboratory's continuing interest in sensorimotor neural activity during unrestrained move-

ments, the project also includes development and fabrication of chronically implantable mechanical transducers, catheters, and connectors. The development of computer programs of general utility for acquisition and analysis of neuroelectric and mechanical records is also included, as well as the development of neuroanatomical material.

[324] Studies in Neuromuscular and CNS Diseases and Their Experimental Models

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Immunocytochemical studies were conducted using specific antibodies to thymic peptides to investigate the interaction of the immune system with the central nervous system (CNS), and peripheral nervous system (PNS).

Results/Implications—Thymosin-beta 4, an immunomodulating thymic polypeptide, was found to be a common antigen shared by macrophages, dendritic lymphoid cells, and the myelin-producing cells in the CNS (oligodendrocytes) and the PNS (Schwann cells).

Prothymosin (a nuclear protein), and thymosin-alpha 1 were found present in astrocytes of normal human brain tissue and could play a role in cell proliferation and gliosis.

The IgM of certain patients with paraproteinemic polyneuropathies has been identified as a specific antibody to acidic glycolipids; intraneural injection of IgM in the sciatic nerve of the cat induced demyelination, suggesting a direct role in the pathogenesis of the neuropathy.

The nature of amyloid protein in patients with "sporadic" amyloid polyneuropathy was identified using

specific antibodies to amyloid proteins: point mutations and direct sequencing of prealbumin genes, the precursor protein, were studied in the amyloid tissue using the polymerase chain reaction.

The mechanism of inflammatory myopathy in monkeys with immunodeficiency (simian AIDS) caused by SRV-1 and SIV-1 retroviruses was studied. Antibodies to myoblasts in tissue culture did not exert a cytopathic effect in the muscle. The role of SIV-1 was similarly studied. The effect of aging on the neuromuscular system of monkeys from age 5 to 25 is being studied, with a detailed morphological and morphometrical analysis of their muscle and nerve biopsies.

The mechanism of muscle regeneration is being studied by examining markers on satellite cells (including the role of adhesion on molecules such as laminin, N-CAM, and ICAM). The monoclonal antibody Leu-19 (NKH) that identifies natural killer cells was found to share common antigenic determinants with the satellite muscle cells. NKH also stains regenerating muscle fiber, and could play a role in muscle regeneration.

[325] The Role of Artificial Sensory Feedback in the Restoration of Motor Control

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Sponsor: *St. Maartenskliniek, Department of Research and Development*

Purpose—Rehabilitation, for a large part, can be seen as a learning process during which patients must reacquire old skills (e.g., walking). Ample evidence exists that feedback plays a crucial role in this process. Most motor tasks performed in natural settings provide the patient immediately with known results. Since the patient with motor dysfunction often also has sensory problems, he is totally dependent on the therapist for information concerning the outcome of his attempts. This dependence is especially true during the first stages of therapy when the task is new, and the primary concern is to understand

what has to be done, and how. This project evaluates the usefulness of several forms of artificial sensory feedback in the first phase of therapy.

Methodology—Portable feedback devices are used which enable the patient to practice also in their home situation during the performance of daily life activities.

Progress—A series of N=1 studies have been performed with patients suffering from the consequences of peripheral neurological lesion.

[326] Pathophysiology of the Anemia of Chronic Renal Failure

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Sponsor: *National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; University of Washington*

Purpose—This project seeks the reasons why erythropoiesis remains suppressed in the majority of maintenance dialysis patients. Several hypotheses are under study which address the possibility of inhibitors remaining in the patient's sera by not crossing the dialysis membrane, or that some aspect of treatment may independently lead to this problem.

Methodology—Studies will seek the presence of hypothesized inhibitors of erythropoiesis in uremic sera. Experiments will also seek to determine if repetitive red cell transfusions may cause the phenomenon, or if aluminum may have an inhibiting role in heme synthesis within bone marrow. The applicability of using a dialyzer membrane of greater porosity will be studied if the presence of inhibitors remaining in uremic sera is demonstrated.

Preliminary Results—It has been found that although a hypoproliferative anemia exists in all patients with chronic renal failure, some patients improve their anemia, though by an unknown means. In normal persons, it has been found that hypertransfusion and phlebotomy cause reciprocal changes in erythropoietin production and red blood cell production, though these effects may be absent or blunted during uremia.

Future Plans/Implications—If the basis for continued suppression of erythropoiesis during dialysis can be elucidated, it may point toward strategies to relieve this very serious consequence of kidney failure, or relieve what may be proven to be a serious side effect of treatment.

[327] PLEXUS: A Knowledge-Based System to Assist with the Diagnosis and Treatment Planning of Brachial Plexus Injuries

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Sponsor: None listed

Purpose—A knowledge-based system is being developed to assist neurologists and neurosurgeons with the diagnosis and treatment planning of patients with a brachial plexus injury (nerve injury in the neck). The reason for developing this system is the very intricate anatomy of the brachial plexus, and the relative unfamiliarity with the possibilities of modern neurosurgical techniques.

Progress—A knowledge-based system has been developed for diagnosis and treatment planning. This system uses production rules for a rough localization of the injury, and then uses a search algorithm to find the exact location of the injury. It has been clinically tested at two Dutch centers of expertise on the subject of brachial plexus injuries. In order to increase the acceptability of the system, improvements have been made to the explanation facilities, and a graphical user interface has been developed for data entry on computer. Work is also being done on more explicit modeling of the knowledge, by means of a formalism using objects and relations.

Results—The rule-based knowledge base has been tested clinically, and has shown to give correct advice for diag-

nosis and treatment plan in 80% of 15 cases. A double-blind test with the system has also been carried out. Although the number of test cases is quite small, we may conclude that the knowledge-based system has a good performance.

Future Plans/Implications—This rule-based system, with graphical interface, will be installed in two clinics for further testing. Modeling of the knowledge in objects and relations will be continued. And finally, a critiquing facility will be incorporated into the system to allow it to react to the physician's own ideas about the diagnosis and treatment plan.

Recent Publications Resulting from This Research

Explanation Improvement to Enhance Acceptance of the PLEXUS System. Van Daalen C, Jaspers RBM, Lecture Notes in Medical Informatics, in Proceedings of AIME 89, 38:286-295, J. Hunter et al. (Eds.). Berlin: Springer-Verlag, 1989.

Modelling the Rehabilitation of Brachial Plexus Injuries: The PLEXUS System. Jaspers RBM, Van Daalen C, Van der Helm FTC, J Med Eng Technol 13:114-118, 1989.

Medical Decision Support: An Approach in the Domain of Brachial Plexus Injuries. Jaspers RBM, PhD diss., Delft University of Technology, 1990.

B. Arthritis

[328] Biochemical Analysis of Synovial Activation in Joint Dysfunction

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Sponsor: VA Rehabilitation Research and Development Service (Project #A052-5RA)

Purpose—The purpose of this study was to answer the following questions: 1) Is synovial cell activation by cartilaginous or metallic particles, metal ions and interleukin-1 mediated by one of the "classical" second messengers, such as cAMP or Ca^{2+} ? 2) Are alterations in protein phosphorylation involved in synovial cell

activation by these mediators? 3) Is the synthesis of collagenase in response to these mediators correlated with changes in the abundance of mRNA for the collagenase gene? and, 4) Does synoviocyte activation by metal ions or metallic particles occur *in vivo* as well as *in vitro*?

Progress/Methodology—We have answered questions 2 and 3, and are now focusing on question 1. We have also begun the *in vivo* work on question 4.

To determine whether changes in protein phosphorylation occur during the cellular activation of synoviocytes, cultures of these cells were equilibrated with ^{32}P -orthophosphate for 3 hours. Cells were then washed and duplicate cultures treated with activators of interest for periods of time ranging from 1 minute to 1 hour. Following these incubations, cells were washed, lysed and their proteins separated by two-dimensional gel electrophoresis employing isoelectric focusing in the first dimension and sodium dodecyl sulfate polyacrylamide gel electrophoresis in the second. Radioactive spots of ^{32}P -labeled proteins were identified by autoradiography and comparisons made between the patterns of phosphoproteins in control and activated cells. As such autoradiograms contained over 800 different spots, comparison proved too complex for the naked eye. Autoradiograms were thus compared by computer. Such analyses confirmed that approximately 40 proteins became newly phosphorylated upon cellular activation, while the phosphorylation of several proteins was decreased upon activation.

Preliminary Results/Implications—Such changes in protein phosphorylation are best explained as a reflection of changes in the activities of one or more protein kinases. As a result, we are presently attempting to identify the kinase or kinases responsible. Best studied in this regard are protein kinases which are activated by cyclic nucleotides, Ca^{2+} alone, or phospholipids and Ca^{2+} . We have consequently devoted considerable effort to determining which, if any, of these might be involved in synovial cell activation. So far, we have been unable to implicate cyclic AMP, cyclic GMP or Ca^{2+} in this response. Furthermore, a detailed and extensive analysis of the possible role of protein kinase C, which depends upon Ca^{2+} and phospholipid for its activity, has failed to identify a role for this kinase in the activation of synoviocytes by the activators we are studying. This is a little surprising since phorbol myristate acetate, a chemical which strongly activates protein kinase C, also strongly activates synoviocytes. These studies are continuing. Of great potential interest is a new, membrane-bound kinase which we have recently identified. The activity of this

kinase appears to correlate with activation of the cells. We expect the characterization and analysis of this kinase to be a major focus of the remainder of this funding cycle.

Since proposing to study the abundance of collagenase mRNA in activated cells, we also have obtained a cDNA probe for the rabbit stromelysin mRNA. These studies have thus been expanded to include measurement of both collagenase and stromelysin mRNAs. Resting cells contain very low levels of both of these mRNA species. Following activation, there is a lag phase of approximately 3 to 5 hours, after which the abundances of both of these messages increase coordinately, reaching steady state levels after 12 to 24 hours. The messages are very stable, remaining at high abundance for at least 48 hours after the removal of the activator. Regardless of the activating agent (particles, interleukin-1, metals) there is always a correlation between the cellular synthesis of collagenase and stromelysin and the cellular abundances of the mRNAs coding for these enzymes. This indicates a pre-translational level of regulation. This is likely to reflect transcriptional regulation although alterations in message stability cannot be theoretically excluded.

Recent Publications Resulting from This Research

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- Approaches to Paramagnetic Separations in Biology and Medicine. Evans CH, Russell AP, Westcott VC, Particulate Sci Tech 7:97-109, 1989.
- Chondrocyte Activation by Interleukin-1: Analysis of the Synergistic Properties of Fibroblast Growth Factor and Phorbol Myristate Acetate. Bandara G et al., Arch Biochem Biophys 274:539-547, 1989.
- Cycloheximide Inhibits the Induction of Collagenase mRNA in Chondrocytes Exposed to Synovial Factors or Recombinant Interleukin-1. Lin CW et al., Agents Actions 27:445-447, 1989.
- Protein Kinase C and Chondrocyte Activation. Hulkower KI, Georgescu HI, Evans CH, Agents Actions 27:442-444, 1989.
- Protein Kinase C and Chondrocyte Activation. Hulkower KI, Georgescu HI, Evans CH, Trans Orthop Soc 14:331, 1989.
- Interleukin-1 and Synovial Protein Kinase C: Identification of a Novel 35kDa Cytosolic Substrate. Hulkower KI et al., Calcif Tiss Int 46(S 2):A33, 1990.
- Studies on the Autocrine Activation of the Synovial Cell Line, HIG-82. Baratz M, Georgescu HI, Evans CH, J Orthop Res (in press).
- Synovial Responses to Metals and Their Possible Involvement in Aseptic Loosening. Evans CH, Ferguson GM, in Metals and Their Alloys in Orthopaedic Surgery, G. Buchhorn, H-G. Willert (Eds.). Stuttgart: Huber (in press).

C. Low Back Pain

[329] Low Back Pain Studies

Malcolm H. Pope, PhD; Martin H. Krag, MD; William Cats-Baril, PhD; Rowland Hazard, MD; Mary Moffroid, PhD; Steven Reinecke, MSME; David Wilder, PhD; Jerry Weisman, MSME; Antonia Clark, MS; Janice Clements, BS
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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The Vermont Rehabilitation Engineering Center (REC), now in its second 5-year funding cycle, is committed to improving the prevention, treatment, and rehabilitation of low back pain through an integrated program of basic and applied research and information services. Specific objectives of the multidisciplinary center include: identification of risk factors for low back injury, pain, and disability; development of new measurement methods for diagnosis and research; evaluation of treatment programs and modalities; worksite assessment and modification; service delivery; information dissemination and training.

Affiliates of the Vermont REC include the Spine Institute of New England (formerly New England Back Center), which operates a comprehensive rehabilitation program for chronic low back patients; and Rehabilitation Technology Services, which provides service delivery to individuals with low back and other disabilities.

Projects/Progress—Several research projects are currently under way in the following areas:

1) **Prediction of Disability and Assessment of Rehabilitation Strategies.** *William Cats-Baril, PhD.* The REC continues its pioneering work on prediction of low back disability and construction of a comprehensive and accessible database on individuals with low back pain. A model has been developed that predicts disability outcome with 83% to 89% accuracy. A questionnaire based on this model is now being used to collect data at sites outside Vermont.

2) **Intervertebral Motion and Muscle Use Detection.** *Martin Krag, MD.* This project was designed to develop a methodology for characterizing intervertebral motion and muscle use patterns in the lumbar spine. The design and fabrication of necessary equipment and software have been completed; *in vivo* testing was begun in early 1990.

3) **Lifting Capacity.** *Rowland Hazard, MD.* A prototype device for measuring lifting ability has been developed. The device, which incorporates an assessment of

subject effort, promises to be a practical, reliable, and inexpensive means of determining lifting capacity for a wide range of occupational health practitioners.

4) **Exercise and Physical Conditioning.** *Mary Moffroid, PhD.* This project comprises several discrete studies designed to study the endurance, eccentric capability, and time to response (to postural shifts) of the muscles surrounding the lumbar spine. Long-range goals include designing effective measurement tools and treatment programs.

5) **Evaluation of Biofeedback in Lumbar Orthoses.** *Malcolm H. Pope, PhD.* Lumbosacral corsets are frequently prescribed for low back pain, although their effectiveness and mechanism of action have not been demonstrated. The project compares the effectiveness of auditory feedback, trunk inclination feedback, and EMG feedback; the project comprises design and testing of devices and two triple crossover studies.

6) **Seating Studies.** *Steven Reinecke, MSME.* A prototype lordotic CPM device has been designed; when incorporated in a typical office chair, it provides continuous motion in the lumbar region. The device is now being tested to determine its efficacy in minimizing back discomfort in both static (office) and vibrational (vehicle) seating environments. An adjustable sit-stand workstation has also been designed and is being tested by back-healthy subjects, as well as back pain patients, to assess its effect on subject fatigue, comfort, and productivity.

7) **Vibration Studies.** *David Wilder, PhD.* With a long-range goal of optimizing work environments that involve vibration, this project was designed to assess the relative contributions of various spinal support structures, seating components, and postures to fatigue and back pain. Worksite assessments are frequently performed to measure amounts of vibration and impact, and recommendations made to minimize their deleterious effects on the spine.

8) **Development of a Workload Assessment System.** *Jerry Weisman, MSME.* A Workload Assessment System is being developed to provide detailed information about

various biomechanical stresses in the workplace. Posture and load can be monitored continuously over the course of the day and analyzed to provide a picture of job task demands. The system will be used to assess job demands across several occupations, in Vermont and elsewhere.

9) Information Services: Publications. *Antonia Clark, MS. Public Relations. Janice Clements, BS.* The REC's Information Services Division comprises a variety of activities in the areas of I & R, publications, education and training, public relations, and research evaluation. A subject-specific bibliographic database on low back pain, called BACKFILES, has been developed to assist researchers and clinicians in locating information about low back research, treatment, and rehabilitation. The Vermont REC offers assistance in locating programs, and provides information search services.

Recent Publications Resulting from This Research

- Biomechanics of the Lumbar Spine. Pope MH, *Ann Med (Helsinki)* 21(5):347-351, 1989.
- Design and Use of a Microcomputerized Real-Time Muscle Fatigue Monitor Based on the Median Frequency Shift in the Electromyographic Signal. Seroussi RE et al., *IEEE Trans Biomed Eng* 36(2):284-286, 1989.
- Factors Affecting the Dynamic Response of the Seated Subject. Pope MH, Broman H, Hansson T, *J Spinal Disord* 3(2):135-142, 1990.
- Functional Restoration with Behavioral Support: A One-Year Prospective Study of Patients with Chronic Low Back Pain. Hazard RG et al., *Spine* 14(2):157-161, 1989.
- Internal Deformations of Intact and Denucleated Human Lumbar Discs Subjected to Compression, Flexion and Extension. Seroussi RE et al., *J Orthop Res* 7:122-131, 1989.

- Internal Fixation of the Lumbrosacral Spine: Experience with the Vermont Spinal Fixator. Krag MH, Chapter 22 in *Lumbar Interbody Fusion: Principles and Techniques of Spine Surgery*, P.M. Lin, K. Gill (Eds.). Rockville, MD: Aspen Publishers, 1989.
- Low Back Pain in Seated Vibration Environments. Wilder DG, Pope MH, in *Understanding and Preventing Back Trauma: Internal Events and Reactions*, K.H.E Kroemer, J.D. McGlothlin, T.E. Bobick (Eds.). Akron, OH: AIHA, 1989.
- Non-Steroidal Anti-Inflammatory Drugs and Low Back Pain. Hazard RG, Buckley L, *J Musculoskel Med* 6(4):64-71, 1989.
- Physiology and Spine Mechanics. Pope MH, Chapter 5 in *Contemporary Care for Painful Spinal Disorders: Concepts, Diagnosis and Treatment*. Philadelphia: Lea & Febiger, 1989.
- Risk Indicators in Low Back Pain. Pope MH, *Ann Med (Helsinki)* 21(5):387-392, 1989.
- Trunk Muscle Electromyography and Whole Body Vibration. Seroussi RE, Wilder DG, Pope MH, *J Biomech* 22(3):219-229, 1989.
- Clinical Instability of the Lumbar Spine. Frymoyer JW, Pope MH, Wilder DG, in *The Lumbar Spine*, J. Weinstein, M. Tile (Eds.). Philadelphia: W.B. Saunders Company, 1990.
- Effects of Axis Placement on Measurement of Isokinetic Flexion and Extension Torque in the Lumbar Spine. Stokes IAF et al., *J Spinal Disord* 3(2):114-118, 1990.
- Occupational Low Back Pain (2nd Edition). M.H. Pope, J.W. Frymoyer, G.B.J. Andersson, D.B. Chaffin (Eds.). Chicago: C.V. Mosby Co., 1990.
- Rehabilitation of the Patient with Chronic Low Back Pain. Hazard RG et al., in *Occupational Low Back Pain (2nd Edition)*, M.H. Pope et al. (Eds.). Chicago: C.V. Mosby Co., 1990.
- Rehabilitation Technology in the Workplace. Weisman J, in *CRC Handbook of Rehabilitation Engineering*, J. Leslie (Ed.). Boca Raton: CRC Press, 1990.
- Demographic Factors Associated with the Prevalence of Disability in the General Population: Analysis of the NHANES I Database. Cats-Baril WL, Frymoyer JW, *Spine* (accepted for publication).
- Identifying Patients at Risk of Becoming Disabled Due to Low Back Pain: The Vermont Rehabilitation Engineering Center Predictive Model. Cats-Baril WL, Frymoyer JW, *Spine* (accepted for publication).

[330] Development of a Computerized Documentation-Data Analysis System for Work Hardening

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Sponsor: National Institute on Disability and Rehabilitation Research; University of Illinois at Chicago

Purpose—The epidemic of disability resulting from low back pain continues to result in tremendous personal, social, and economic costs. The need for effective rehabilitation for low back pain patients has led to the proliferation of treatment programs. Unfortunately, we know relatively little about the effectiveness of rehabilitation for the low back pain patient. While rehabilitation programs accumulate volumes of data on low back pain patients, this data is generally not used for research. This problem will be addressed by developing a computerized,

clinical data-management system for work hardening, capable of managing a clinical database for research purposes while supporting the clinical documentation responsibilities of the rehabilitation therapist.

Methodology—A Documentation-Data Analysis System (D-DAS) has been designed to manage data for low back pain patients in work hardening rehabilitation programs. Demographic, initial evaluation, discharge evaluation, and follow-up variables have been selected to test specific

research questions and to support the program evaluation and documentation needs of the clinic. Forms and procedures for data collection have been developed and manuals have been written. Computer programs have been written using PC-SAS, a research-level statistical software package for the personal computer. These programs are being designed for data entry and documentation production from patient data collected at initial evaluation, discharge evaluation, and follow-up interview. D-DAS is being designed to have database, graphics, and statistical capabilities to manage patient data for research and program evaluation purposes.

Progress—Data collection instruments have been developed and are presently being used at two clinical sites. User-friendly data-entry screens have been developed for demographic and initial evaluation data from patients. D-DAS has been demonstrated to have the database

(e.g., electronic access to patient data), graphics, and statistical capabilities proposed. Using the "mail merge" capabilities of PC-SAS, a text-based report for the medical records has been developed which incorporates approximately 120 variables from a PC-SAS data set (e.g., patient name, referring physician, pain ratings, maximum weight lifted bilaterally, etc.). Pilot data has been collected on 25 patients and data entry and report production have been revised on the basis of this study.

Future Plans/Implications—Discharge and follow-up data entry screens and documentation reports are being developed. We plan to field test the software at one or two sites during the next few months. Data collection from three sites is planned for initial studies of predictors for return to work, as well as initial studies on the efficacy of work hardening treatment for the low back pain patient.

[331] Low Back Pain and Sciatica: Factors for Success of Therapy

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Low back pain and sciatica are a complex clinical problem which causes great suffering, disability, and expense. The two constitute the greatest single clinical volume for both neurosurgery and orthopedics. Intradiscal therapy has recently been added to surgery and conservative care for management. Long-term effects of these drugs are not known, and definitive criteria to accurately predict success or failure of therapy are not defined. We plan to study a broadly-based population of patients to determine the factors associated with success (or failure) of the three major forms of therapy—surgery, intradiscal injection, and conservative care.

Methodology—Data from multiple centers representing neurosurgery and orthopedics will be accumulated on physical and X-ray findings, as well as social, demographic, and psychologic factors in these patients. Outcome will be evaluated for all treatments and correlated with these multivariant factors. Long-term evaluations will proceed for 5 years to compare the eventual outcomes, and the cost of care will be compared. The goal is to appropriately match outcome with treatment.

D. Swallowing Disorders

[332] Assessment of the Swallow Reflex in Patients with Dysphagia

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Sponsor: VA Rehabilitation Research and Development Service (Project #C443-RA)

Purpose—Our purpose has been to develop a nonradio-graphic method by which investigators can study certain aspects of swallowing. Ultimately, the results of this investigation will provide information to assist in determining appropriate rehabilitation techniques and evaluating progress for patients with dysphagia.

Of particular interest was application of the electroglottograph (EGG) to evaluation of certain temporal aspects of the pharyngeal stage of swallowing (swallow reflex). The EGG was developed as a noninvasive, electrical impedance method of measuring vocal fold contact during phonation and has not been used previously to measure the slow varying laryngeal movements that occur during swallowing.

Progress/Preliminary Results—We have studied the transfer function of two EGGs. The Fourcin EGG was analyzed first; at low frequencies, the output was found to be the derivative of the changes in neck impedance. This was not the case in the higher frequencies associated with the speech range; at higher frequencies, the EGG output directly represented the changes in neck impedance. We analyzed the Rothenberg EGG and found the output to be directly related to changes in neck impedance at all frequencies.

We made simultaneous measures of EGG output, oropharyngeal pressure, and videofluoroscopic images during swallowing. We found that the time during which the larynx was elevated always exceeded the duration of the pharyngeal pressure wave; the larynx began to elevate before or shortly after the initiation of the tongue-driving pressure, and always before the onset of the pharyngeal pressure wave. In all subjects, the pharyngeal pressure wave returned to baseline prior to the onset of laryngeal descent. From the EGG output, the onset of laryngeal movement and the time of maximum laryngeal elevation can be identified; however, placement of the electrodes is crucial.

The EGG can be used clinically as a method of evaluating delays in onset of initiation of the swallow reflex. It can also be used as a biofeedback device for

teaching patients how to perform the Mendelsohn maneuver (a swallowing posture that aids in prolonging opening of the cricopharyngeus muscle and in keeping the larynx elevated).

Two electromyographic studies have been performed. We first studied EMG activity in the superior pharyngeal constrictor muscle of normal subjects while they performed a series of reflexive and nonreflexive tasks. The nonreflexive tasks involved both speech and nonspeech activities, and the reflexive tasks involved swallowing and gagging. The reflexive tasks resulted in the greatest EMG activity. The gag produced about 60% of the activity produced by a swallow. The hierarchy of EMG activity was well-defined and suggested that certain voluntary tasks may be useful in reducing the potential for disuse atrophy in patients with pharyngeal constrictor weakness.

The second study looked at the duration of EMG activity in the thyroarytenoid, cricothyroid, and superior pharyngeal constrictor muscles of normal subjects during swallowing. Preliminary analysis indicates that EMG activity in the superior pharyngeal constrictor muscle is approximately 76 ms longer than EMG activity in the thyroarytenoid, and 94 ms longer than that from the cricothyroid muscle during swallow. Average duration of superior pharyngeal constrictor activity increased as bolus size increased. Thyroarytenoid activity was shorter for dry swallows but approximately the same for 10 cc and 20 cc bolus swallows.

We also studied the relationships between oral stage dysphagia, vallecular stasis, reduced hyoid elevation and movement, and position of the epiglottis in 330 dysphagic patients who had a swallow reflex. Multivariate analysis revealed significant relationships between all variables except oral involvement and deviant epiglottic function. Four types of epiglottic function that deviated from the description of normal position or motion during swallowing were identified.

Future Plans—We intend to begin development of a swallowing model.

Recent Publications Resulting from This Research

Electrical Activity in the Superior Pharyngeal Constrictor Muscle During Reflexive and Non-Reflexive Tasks. Perlman AL, Luschei ES, DuMonde CE, *J Speech Hear Res* 32:749-754, 1989.

Frequency Response of the Fourcin Electrolottograph and Measurement of the Temporal Aspects of Laryngeal Movement

During Swallowing. Perlman AL, Liang X, *J Speech Hear Res* (in press).

Use of the Electrolottograph for Measurement of Temporal Aspects of the Swallow: Preliminary Observations. Perlman AL, Grayhack JP, Dysphagia (in press).

[333] Swallowing Dysfunction in Nephropathic Cystinosis

Barbara C. Sonies, PhD; Evan F. Ekman, BA; Hans C. Andersson, MD; Megan D. Adamson, MD; Stephen G. Kaler, DMD, MD; Thomas C. Markello, MD, PhD; William A. Gahl, MD, PhD

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Sponsor: *National Institutes of Health*

Purpose—Nephropathic cystinosis causes renal failure in most patients at approximately 10 years of age. This can be prevented or retarded by cystine-depleting therapy with oral cysteamine. Patients who do not receive adequate cysteamine therapy can undergo renal transplantation, but the accumulation of cystine continues in other organs, resulting in various clinical abnormalities. We report age-related swallowing dysfunction in patients with nephropathic cystinosis.

Methodology—We studied 43 patients with cystinosis (24 who had received a renal transplant, and 19 who had not), 3 to 31 years of age. Oral motor function was assessed by a cranial-nerve oral sensorimotor examination, and an oral motor index was calculated for each patient. The oral phase of swallowing was assessed by ultrasonography, and the pharyngeal and esophageal phases were evaluated by videofluoroscopy.

Results—Approximately half the patients were slow eaters. Oral motor dysfunction, reflected by a higher oral

motor index, increased with age. Speech, oral structure and anatomy, and tongue and lip strength were particularly affected. Seven of nine patients, 21 to 31 years old, had abnormalities in all three phases of swallowing; the deficits were variable in younger patients. In 28 patients with cystinosis, the mean (\pm SD) duration of oropharyngeal swallowing, or a dry swallow (3.06 ± 1.06 seconds), was longer than in 14 normal subjects (1.89 ± 0.57 seconds; $P < 0.001$). This prolongation reflected impairment of the initiation phase of swallowing.

Implications—Swallowing dysfunction is a late complication of nephropathic cystinosis, probably related to muscular dysfunction. Changes in the consistency of foods, swallowing exercises, and long-term cysteamine therapy should be considered for patients with cystinosis who have difficulty in swallowing.

Recent Publications Resulting from This Research

Swallowing Dysfunction in Nephropathic Cystinosis. Sonies BC et al., *New Eng J Med* 323(9):565-570, 1990.

E. Vascular Disorders

[334] Postoperative Thromboembolism in Surgical Patients

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Sponsor: National Heart, Lung, and Blood Institute, National Institutes of Health

Purpose—This study encompasses a series of controlled prospective clinical trials designed to investigate the pathophysiology of thrombotic states and related conditions, and the pharmacology of new antithrombotic and hemostatic drugs. Two of the five trials are related to geriatric rehabilitation.

Methodology/Implications—One trial measures the degree to which venous thromboembolism can be prevented in elderly patients with fractures of the hip by administration of the heparin-like compound Organon 10172. A second trial examines the potential of activated

recombinant protein C to act as an antithrombotic agent in phlebography-diagnosed patients who are at high risk of developing postoperative venous thromboembolism: specifically, it investigates the efficacy and safety of the intraoperative and postoperative infusion of the protein which is prepared by recombinant DNA techniques, with a view to prevention of venous thrombosis in patients undergoing total hip replacement.

Recent Publications Resulting from This Research

Heparin for Prophylaxis of Venous Thromboembolism. Salzman EW, *Ann NY Acad Sci* 556:371-377, 1989.

[335] Basic and Clinical Studies of Coagulation Proteins

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Sponsor: National Heart, Lung, and Blood Institute, National Institutes of Health

Purpose—Warfarin is an established, effective prophylaxis against deep vein thrombosis in the setting of cemented total hip replacement, but its general use has been hindered by a perceived risk of increased bleeding complications. This study investigates whether the safer application of external pneumatic compression is as effective as warfarin anticoagula-

tion in prophylaxis after noncemented total hip replacement.

Preliminary Results—Preliminary observations indicate that thromboembolic disease in patients receiving noncemented prostheses is lower than in those receiving cemented prostheses.

[336] Emphysema—Physiologic Effects of Nutritional Support

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Sponsor: National Heart, Lung, and Blood Institute, National Institutes of Health

Purpose—In this investigation, the role of malnutrition in the pathogenesis of ventilatory dysfunction in emphysema will be assessed and the effectiveness of nutritional support in reversing this dysfunction determined. The chronic weight loss often found in patients with chronic

obstructive pulmonary disease (COPD) has an adverse effect on prognosis. There is a positive correlation of significant malnutrition with emphysema and, moreover, the degree of malnutrition is correlated with some aspects of pulmonary function.

Preliminary studies also suggest that malnutrition has an adverse effect on ventilatory muscle strength. In addition, weight loss and decrement in pulmonary function are not monotonic in these patients, but often occur as a "step change." In a recently completed pilot study, it was demonstrated that in a controlled setting these patients will gain weight, and that this weight gain is associated with improvement in peripheral and ventilatory muscle strength.

Methodology—Using a carefully controlled and randomized study design and monitored nutritional supplementation, the physiologic effects of nutritional repletion on the ventilatory function of malnourished emphysema patients will be determined. Complete pulmonary function testing, exercise, and 12-minute walk performance will be measured before and after nutritional intervention. In order to evaluate the effects of malnutrition and subsequent nutrition therapy on ventilatory muscle strength and function, maximal transdiaphragmatic, inspiratory and expiratory pressures will be measured before and after nutritional supplementation.

Handgrip strength, before and after nutritional intervention, will be used as an index of overall muscle

strength. By careful interviewing and close follow-up, the benefits of nutritional therapy will be examined for their effect on quality of life and requirements for hospitalization of these patients.

Implications—From the data collected in this investigation, it may be possible to develop a strategy by which nutritional intervention can be developed for COPD patients. If, as our pilot study suggests, muscle strength can improve with nutritional intervention, perhaps this could decelerate the predictable decline of ventilatory function in these patients.

Recent Publications Resulting from This Research

Body Weight in Chronic Obstructive Pulmonary Disease: The National Institutes of Health Intermittent Partial Pressure Breathing Trial. Wilson DO et al., *Am Rev Respir Dis* 139:1435-1438, 1989.

Oxygen Consumption of the Respiratory Muscles in Normal and Malnourished COPD. Donahoe M et al., *Am Rev Respir Dis* 140:385-391, 1989.

Metabolic Rate and Weight Loss in Obstructive Lung Disease. Wilson DO et al., *J Parenter Enteral Nutr* 14(1):7-11, 1990.

[337] Trial of Inspiratory Muscle Rest and Exercise in Chronic Obstructive Lung Disease

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Sponsor: *National Heart, Lung, and Blood Institute, National Institutes of Health*

Purpose—Dyspnea and disability in chronic obstructive lung disease (COLD) may be a result of inspiratory muscle dysfunction. If so, many patients with severe COLD may have chronic inspiratory muscle fatigue which can be treated by ventilatory muscle rest (VMR). A randomized controlled clinical trial has been developed to assess whether VMR will: 1) improve exercise performance; 2) alleviate the sensation of dyspnea; and, 3) improve measurable quality of life for patients with severe irreversible COLD.

Preliminary Results—Preliminary data, from uncontrolled trials, have shown substantial improvements

resulting from VMR. The effectiveness of this intervention in a more rigorously controlled investigation will be assessed before its diffusion renders a controlled study difficult. If successful, this new form of low-cost therapy may revolutionize the rehabilitation of patients with severe COLD.

Recent Publications Resulting from This Research

Effect of Nutritional Status on Exercise Performance in Patients with Chronic Obstructive Pulmonary Disease. Gray-Donald K et al., *Am Rev Respir Dis* 140:1544-1548, 1989.

[338] Training Level Versus Cardiac Adaptations in Patients with Coronary Heart Disease

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Sponsor: *National Heart, Lung, and Blood Institute, National Institutes of Health*

Purpose—Insufficient information is available for selection of the most appropriate exercise levels for training and rehabilitation of coronary heart disease (CHD) patients with varying degrees of severity. Several studies indicate that vigorous exercise can be safely performed, and that such training can elicit cardiovascular adaptations in selected CHD patients. In this study, the effects of low and high levels of regular supervised training are compared. Over a 2-year treatment period, cardiac adaptations among 200 patients with CHD documented by arteriogram or myocardial infarction will be examined. The hypothesis that exercise of appropriate intensity and duration will safely affect cardiovascular adaptations will be tested. Recruitment, training, and evaluation will take place at two affiliated clinical centers with long experience in cardiac rehabilitation.

Methodology—Eligible men will enter a pre-randomization program designed to identify and eliminate persons with adherence problems or poor motivation. Participants will be randomly assigned to high or low exercise groups, and will be evaluated periodically with two independent exercise techniques: supine ergometer exer-

cise and upright maximal exercise testing with gas exchange measurements. Both tests will include two-dimensional echocardiography pre- and post-exercise, as well as during exercise with the ergometer. Comparison of the value of the two exercise techniques will yield important clinical information. The major outcome assessed will be the change in exercise ejection fraction at one year. Additional observations reflecting ventricular function, myocardial oxygen delivery capacity, and metabolic alterations over time by treatment group will be noted.

Implications—Results of this study will contribute to a better understanding of long-term cardiac adaptations with different physical activity levels and possibly the efficacy of secondary prevention. Implications may be forthcoming for exercise prescriptions and patient evaluation in cardiac rehabilitation programs.

Recent Publications Resulting from This Research

Reproducibility of Two-Dimensional Exercise Echocardiography. Oberman A et al., *J Am Coll Cardiol* 4:923-928, 1989.

[339] Effects of Social Support on Recovery from Coronary Artery Bypass Graft Surgery

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Purpose—The purpose of this study is to enhance understanding of how different types of social support affect patients and their spouses following coronary artery bypass graft surgery (CABGS). Different types and sources of social support will be identified. The relationship of the type of support to health outcome and to spouses' psychological functioning will be determined.

Methodology/Preliminary Results—Data are being collected by interview within a short time prior to surgery

and at 1, 4, 12 months, and 2 years after surgery. The outcome will be evaluation of various parameters, including a profile of mood states, a sickness impact profile (for the patients), a symptom check list (for spouses), and marital satisfaction. Preliminary analyses suggest that social support is a moderate predictor of outcome for the spouse, but less so for the patient.

[340] Randomized Trial of Rehabilitation in Chronic Obstructive Pulmonary Disease

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Purpose—Rehabilitation programs for patients with chronic obstructive pulmonary disease (COPD) are common in clinical care throughout the western world. However, the efficacy of these programs has not been evaluated in randomized experimental studies that have followed patients longer than one year, or with outcome measures of important quality-of-life and psychosocial variables.

Progress/Methodology—In this trial, patients have been randomly assigned to comprehensive rehabilitation or to an education control group. The 119 patients participating in the program were evaluated prior to treatment, and after 2, 6, 12, 18, and 24 months. Outcome measures included both psychosocial and physiological variables. The psychosocial measures included a quality of well-being scale, measures of self-efficacy expectations, depression, and social support. The physiological measures included: pulmonary function tests, maximum exercise tolerance with measures of expired and arterial blood gases, and endurance exercise performance. In addition, perceived symptom ratings were taken with each exercise test. Data from the first year of follow-up have been evaluated. Some significant differences in outcomes between the comprehensive rehabilitation protocol and the patients' education protocol have been found.

Future Plans—It is proposed that this follow-up be extended for four additional years. Physiological variables will be evaluated every other year. Psychosocial measures will be taken each year. Using the quality of life outcome data, and data obtained on costs, we will construct a policy model evaluating the cost/utility of the various rehabilitation interventions.

Recent Publications Resulting from This Research

- Interday Reliability of Function Assessment for a Health Status Measure: The Quality of Well-Being Scale. Anderson JP et al., *Med Care* 27:1076-1084, 1989.
- Prediction of Maximum Exercise Tolerance in Patients with Chronic Obstructive Pulmonary Disease. (Abstract) Carlson DJ, Ries AL, Prewitt LM, *Chest* 96:232S, 1989.
- Pulmonary Rehabilitation. Ries AL, in *Manual of Clinical Problems in Pulmonary Medicine*, 3rd ed., R.A. Bordow, K.M. Moser (Eds.). Boston: Little, Brown & Co., 1989.
- Experimental Evaluation of Rehabilitation in Chronic Obstructive Pulmonary Disease: Preliminary Results on Exercise Tolerance and Health Status Outcomes. Toshima MT, Kaplan RM, Ries AL, *Health Psychol* 9:237-252, 1990.
- The Functional Effects of Social Relationships on Chronic Illness and Disability. Kaplan RM, Toshima MT, in *Social Support: An Interactional View*, 427-453, R. Sarason, I. Sarason, G.R. Pierce (Eds.). New York: John Wiley & Sons, 1990.
- The General Health Policy Model: An Integrated Approach. Kaplan RM, Anderson JP, in *Quality of Life Assessment in Clinical Trials*, 131-149, B. Spilker (Ed.). New York: Raven Press, Ltd., 1990.
- Pulmonary Rehabilitation. Ries AL, in *Geriatric Rehabilitation*, 107-120, B. Kemp, K. Brummel-Smith, J.W. Ramsdell (Eds.). Boston: College-Hill Press, 1990.
- A Comparative Study of Psychosocial Aspects of Adults with Cystic Fibrosis and Their Health Peers. Shepherd SL et al., *Chest* (in press).
- Adherence in the Patient with Pulmonary Disease. Kaplan RM, Ries AL, in *Pulmonary Rehabilitation: Guidelines to Success*, 2nd ed., J.E. Hodgkin, C.W. Bell, G. Connors (Eds.). Philadelphia: J.B. Lippincott Company (in press).
- Compliance in Medical Care: Reconsideration of Self-Predictions. Kaplan RM, Simon HJ, *Ann Behav Med* (in press).
- A General Health Policy Model: Applications of New Health Indicators in Studies of Aging. Kaplan RM, Anderson JP, in *Frailty in the Aged*, M. Ory, R. Weindrich (Eds.). New York: Springer-Verlag, Inc. (in press).
- Quality of Well-Being Before and After Ciprofloxacin Treatment of Pulmonary Exacerbation in Cystic Fibrosis. Orenstein DM et al., *Chest* (in press).

[341] Strategies for Promoting Adult Asthma Self-Management

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Sponsor: *National Heart, Lung, and Blood Institute, National Institutes of Health*

Purpose—Recently, a number of interventions have been initiated to promote self-management skills in adults with asthma. One of these, the Asthma Self-Management Program of the University of Alabama at Birmingham (UAB) is based on a patient self-help workbook that is combined with a specific protocol for training patients in its use, and for providing continuing encouragement to maintain self-management skills. This approach has been compared with a “usual care” approach in which subjects received a standard set of routinely available asthma education pamphlets. Because such pamphlets frequently are a part of normal care, it is important that interventions be compared to them rather than to the complete absence of patient education. The UAB Self-Management Program is information-rich and professionally labor-intensive, and evaluation efforts to date have involved only a single sample with a relatively short follow-up period (12 months). It is now appropriate to measure interventions that are more applicable in community practice settings and that involve longer follow-up periods.

Progress/Methodology—Another approach, the “Core Elements Intervention,” has been developed. The development of this protocol will be guided by existing data available on diffusion of innovations and will use “Focus Groups,” composed of physicians in community-based practice.

Procedures for enhancing medication adherence and appropriate self-monitoring with peak flow meters will be stressed, and the protocol will include systematic

follow-up procedures for encouraging and sustaining self-management skills.

A prospective randomized control study will be used to compare approaches over a 2-year period. Outcomes in the following areas will be assessed: 1) functional status; 2) knowledge of asthma; 3) adherence to recommended treatment regimens; 4) psychological influences on and reactions to asthma; and, 5) health care utilization.

Recent Publications Resulting from This Research

- Assessing the Use of Metered Dose Inhalers by Adults with Asthma. Manzella BA et al., *J Asthma* 26:223-230, 1989.
- Improving Self-Management Skills of Adults with Asthma. Bailey WC et al., *Am Rev Respir Dis* 139:A144, 1989.
- Learn Asthma Control in Seven Days: A Step-by-Step Guide Proven Effective in Research Studies Conducted at the University Hospital, UAB. Bailey WC, Manzella BA, Birmingham, AL: University of Alabama Board of Trustees, 1989.
- Patient Characteristics Relevant to Effective Self-Management: Scales for Assessing Attitudes of Adults Toward Asthma. Richards JM et al., *J Asthma* 26:99-108, 1989.
- Controlling Asthma: A Brief Guide. Bailey WC, Manzella BA, Birmingham, AL: University of Alabama Board of Trustees, 1990.
- Characteristics and Correlates of Asthma in a University Clinic Population. Bailey WC et al., *Chest* (in press).
- Evaluation of the Efficacy and Cost Effectiveness of Health Education Methods to Increase Medication Adherence Among Adults with Asthma. Windsor RA et al., *Am J Public Health* (in press).
- Peak Flow Meters: Are They Monitoring Tools or Training Devices? Reeder KP et al., *J Asthma* (in press).
- A Randomized Trial to Improve Self-Management Practices of Adults with Asthma. Bailey WC et al., *Arch Intern Med* (in press).

[342] Application of Self-Management System to Asthmatic Adults

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Sponsor: *National Heart, Lung, and Blood Institute, National Institutes of Health*

Purpose—This investigation applies a self-management system to a population of adults with asthma. The foundation of the system, “Living with Asthma,” has been thoroughly tested with asthmatic children and, in pilot studies, with adults afflicted by the disorder.

Specific aims of the investigation include the following: 1) to thoroughly test the proven fundamentals in 120 adults afflicted with asthma; and, 2) to carefully test and evaluate the results using a number of dependent determinations, including paper-and-pencil instruments, pulmonary

physiology measures, activity restriction changes, medication scores, severity of attack measures, and socioeconomic changes.

Methodology—The basic design consists of a randomized control group in which patients with a confirmed diagnosis of asthma are randomly assigned to treatment or control conditions. All participants, however, will receive self-management training. All subjects will be followed for at least one year to determine the effectiveness of the program over time.

The data will be analyzed by appropriate parametric statistical procedures. At the conclusion of the investigation, all data will be reported so that it may effectively assist physicians in teaching self-management skills to their patients as a practical and cost-effective way to control asthma.

Recent Publications Resulting from This Research

- Asthma. Creer TL, Kotses H, in *Handbook of Child Psychopathology*, 2nd ed., 341-357, T.H. Ollendick, M. Herson (Eds.). New York: Plenum, 1989.
- The Effects of Antihistamines on Electrophysiological and Behavioral Measures of Cognition. Shucard DW, Creer TL, *J Allergy Clin Immunol* 84:284-285, 1989.
- The Effects of Theophylline on Cognitive and Behavioral Performance. Creer TL, McLaughlin JA, *J Allergy Clin Immunol* 83:1027-1029, 1989.

- Living with Asthma: Part II. Beyond CARIH. Creer TL, Kotses H, Reynolds RVC, *J Asthma* 26:31-52, 1989.
- The Practise of Behavioural Medicine. Creer TL, Wigal JK, 211-233, J. Wardle, S. Pearce (Eds.). London: The British Psychological Society and Oxford University Press, 1989.
- Psychological Problems Associated with Drug Therapy in Childhood Asthma. Creer TL, Gustafson KE, *J Pediatr* 115:830-855, 1989.
- A Reinterpretation of Psychologically-Induced Airways Changes: from Asthma to Activation. Kotses H, Hindi-Alexander M, Creer TL, *J Asthma* 26:53-63, 1989.
- The Revised Asthma Problem Behavior Checklist. Creer TL et al., *J Asthma* 26:17-29, 1989.
- Asthma. Creer TL, Reynolds RVC, in *Handbook of Clinical Behavioral Pediatrics*, M. Herson, V.B. Van Hasselt (Eds.). New York: Plenum (in press).
- Asthma. Creer TL, Reynolds RVC, in *Psychological Aspects of Developmental and Physical Disabilities: A Casebook*. M. Herson, V.B. Van Hasselt (Eds.). Beverly Hills, CA: Sage Publications (in press).
- Asthma Treatment Programs for Adults and Children. Creer TL, Kotses H, Reynolds RVC, in *Handbook of Clinical Psychology in Medical Settings*, J.J. Sweet, R.H. Rozensky, S.M. Tovian (Eds.). New York: Plenum (in press).
- A Critique of 19 Self-Management Programs for Childhood Asthma: Part I. The Development and Evaluation of the Programs. Wigal JK et al., *Pediatr Asthma Allergy Immunol* (in press).
- A Critique of 19 Self-Management Programs for Childhood Asthma: Part II. Comments Regarding the Scientific Merit of the Programs. Creer TL et al., *Pediatr Asthma Allergy Immunol* (in press).
- The Effect of Suggestion on the Total Respiratory Resistance of Healthy Individuals. Wigal JK, Kotses H, Creer TL, *J Psychosom Res* (in press).
- The Prevalence and Costs of Childhood Asthma. Creer TL et al., *Am J Asthma Pediatr* (in press).

[343] Vibration Sense and Tarsal Disintegration

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Purpose—It is clear that loss of sensation is an important factor in the etiology of tarsal disintegration. However, the necessary degree and modality of this sensory loss have not been determined. The biothesiometer and Semmes-Weinstein monofilaments represent quantitative methods of sensory assessment which can detect small changes in sensory ability, even in situations where this ability is already significantly impaired. The purpose of this study was to assess the role of loss of vibration and pressure sensation in the etiology of the process of tarsal disintegration (TD).

Progress/Methodology—Twenty-one patients having tarsal disintegration were studied. The disintegration was graded as early (one bone involved, with or without arch

collapse); intermediate (more than one bone involved, with arch collapse); late (anatomic disconfiguration and ectopic calcification); or advanced (separation of fore- and hindfoot, or involvement of ankle mortise).

Measurements were first made of pressure sensation using Semmes-Weinstein monofilaments. Sensation was tested on the base of the great toe, and the first and fifth metatarsal heads (the most common sites for plantar ulceration). The highest threshold determined for these three areas was taken as the threshold for the foot. Patients unable to feel even the strongest stimulus (6.65 monofilament) were recorded as negative.

The biothesiometer was then used to assess vibration sensory thresholds on the base of the great toe and the medial malleolus. The amplitude of vibration of the

probe was increased until the patient could first feel sensation. This was repeated twice: the mean threshold for the great toe and the medial malleolus being added together to produce the value for each foot.

Both feet were measured using these criteria. The foot which had not undergone disintegration was used as a control.

Results—Of the 21 patients examined, 12 had early changes of TD, 6 were of intermediate, 2 of late, and 2 of the advanced variety of TD.

It was observed that the group with TD showed a significantly higher vibration threshold than the group having no changes of TD. Most of the involved feet (18 out of 21) had a threshold value above 12 microns. Thus, in a population of highly insensitive feet, vibration sensation is more severely impaired in those with TD.

The majority of feet in both involved and noninvolved subsets (18 out of 21, and 8 out of 15, respectively), were unable to detect even the strongest stimulus delivered by a Semmes-Weinstein monofilament.

On the whole, no correlation was observed between the duration of disease and sensory thresholds. However,

the majority of patients having disease of more than 10 years' duration had a threshold value of greater than 20 μ M.

No correlation was found between the stage of TD and loss of vibration or pressure sensation, because TD is also related to many other factors of mechanical stress and strains, injuries, infection, weightbearing, etc. This corresponds to the theory that the patterns of disintegration are determined by the posture of mechanical stress in an intact, but insensitive, foot. It is suggested that once a certain degree of sensory loss has occurred, the process may continue regardless of further sensory changes.

Implications—From this small study it is not possible to give information as to a threshold above which disintegration becomes more likely; but significantly, most of the involved feet had a threshold above 12 microns. It is suggested that such a group of patients might be at a higher risk of disintegration of the tarsus, and this should form the basis of a prospective study. Thus, vibration sense measurement using a biothesiometer may be a valuable clinical test in the investigation and follow-up of patients having insensitive feet, and who are at high risk of developing TD.

[344] Motor Units in the Tibialis Anterior Muscle Six Months After Self-Reinnervation

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Sponsor: *National Institute of Neurological Diseases and Stroke, National Institutes of Health*

Purpose—Motoneurons innervate skeletal muscle in a very precise manner during development. The purpose of this work is to study the specificity with which motor axons innervate muscle after complete lesions to the nerve.

Methodology—In the right and left hindlimb of seven adult cats, the nerve branch innervating the anterior compartment of the tibialis anterior (TA) was cut near the muscle and the epineurium resutured, with an attempt made to maintain the original orientation between the proximal and distal ends of the nerve branches. Six months after the nerve was cut and repaired, a single motor unit from the TA in each limb was characterized physiologically and subsequently depleted of its glycogen through repetitive stimulation of a functionally isolated ventral root filament. The location of glycogen-depleted motor unit fibers was mapped in cross-sections taken along the length of the muscle. The following anatomical

measurements were obtained for glycogen-depleted motor units: innervation ratio (IR), mean fiber cross-sectional area (CSA), and specific tension (ST). In addition, spatial analyses were performed to quantify the distribution of motor unit fibers within a single cross-section.

Progress/Results—During the process of self-reinnervation of the tibialis anterior, motor axons (especially the fast motoneurons) tended to innervate more muscle fibers than normal, resulting in large force-producing units. The motor unit fibers in these large units tended to be clustered in groups and had a greater number of adjacencies among motor unit fibers than is observed in normal units. In addition, the anatomical data revealed a strong correlation between maximum force and innervation ratio ($r=0.92$). A stepwise linear regression showed that innervation ratio was the primary determinant of the maximum force in a motor unit.

X. Oncology

For additional information on topics related to this category see the following Progress Reports: [319], [324], [404], [405], [565].

[345] Montana Family Cancer Project

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Purpose—The purpose of the Montana Family Cancer Project is to develop models for cancer management in the home from the experiences of patients and caregivers living in a large rural western state. The dependent variable, family well-being, is predicted from the independent variables of disease, individual, family and community characteristics, patient status, and informal, family, and formal caregiving.

Methodology—Data are gathered from patients, caregivers, and surviving caregivers by telephone and written surveys. Health care delivery data has been gathered from the Montana Association of Home Health Agencies; patient cancer site and stage at diagnosis is verified with oncologists. The American Cancer Society, Montana Division, Inc., the five regional Cancer Treatment Centers, and 14 oncology practices throughout the state have assisted in participant recruitment by direct mailing. Radio, TV, and newspapers have assisted with articles, interviews, and Public Service Announcements. As of August, 1990, 816 families had volunteered to participate.

At present, only preliminary descriptive data are available since the Project is still collecting Phase 1 data. A computer-assisted telephone interview (Phase 1) was developed to gather data on disease, individual/family, and community characteristics. Written questionnaires (Phase 2) are used to gather more detailed data on patient status and informal, family, and formal caregiving as well as the dependent variable, family well-being. Focus groups were conducted with surviving caregivers and health care providers to ascertain content areas for these questionnaires. The questionnaires were pilot-tested and refined with the input of health professionals and patients. The following tools are used: Demands of Illness Inventory; Cancer Needs Survey; Archbold CRS; Family Apgar; Personal Resource Questionnaire; Symptom Distress Scale; CES-D; Demands Scale; Health Service Utilization; Activity Inventory; and Health Status. Time of completion ranges from 25 to 45 minutes.

Progress—Return rates with a postcard and phone-prompt approach 72%. Those families entering Phase 2 (66% of those completing Phase 1) have a mean age of 58.4 years for the careprovider and 59.8 years for the person with cancer. Slightly over half (53%) of careproviders are men; 56% of patients are women. The most frequent cancers are lung, breast, prostate, and colon, which represent 58% of the cancer sites. Patients have varied levels of care needs: 20.3% high level, 19.0% medium level, 30.4% low level, and 30.2% minimal level. Those with the highest levels of care needs are the 21-30 and the 71-80 year-old age groups. The average family income is \$17,000 to \$20,000, with 68.5% of the families living on farms/ranches or in towns with less than 15,000 population. Distance to health care for cancer is a major factor as families travel an average of 163.8 miles round trip for cancer treatment, and average of 191 miles round trip to their oncologist.

Future Plans—Additional funding will be used to conduct a secondary analysis of data gathered from older participants. This information will be prepared as a special report to the Andrus Foundation of the American Association for Retired Persons in July, 1991. Supplemental funding from the National Cancer Institute (NCI) and the College of Nursing, Montana State University, has allowed for the development of questionnaires adapted for patients managing cancer without a caregiver in the house and for those caregivers who have lost a loved one to cancer. These two groups were initially unable to participate in Phase 2; however, enrollment and Phase 1 data indicated the need to gather data from this sizable population.

Phase 3 data collection commenced in January, 1991. Change over the course of 10 months of cancer management is assessed by a telephone interview to gather patient status data, and written questionnaires are used to gather data for the other variables.

[346] Cricopharyngeal Myotomy Study

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—This study will attempt to answer on a prospective basis whether performance of a cricopharyngeal myotomy improves swallowing. This surgical procedure has been purported to improve dysphagia from a variety of illnesses.

Progress—A total of 46 patients have been enrolled in this multi-institutional trial. These patients have

squamous cell carcinoma involving the supraglottic larynx and base of tongue sites. The patients are randomized between cricopharyngeal myotomy versus no myotomy. The quality of collected data, primarily videofluoroscopy, appears to be more than satisfactory. Additional institutions have been recruited to increase patient accrual.

[347] Promoting Patient Self-Care in Head and Neck Cancer

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—The goal of this longitudinal randomized clinical trial is to evaluate two nursing care strategies designed to promote self-care in patients receiving their initial medical nonsurgical treatment for head and neck cancer. The study will first examine the effectiveness of a sequential patient education program. It will also determine if the benefits of the educational program are enhanced by the addition of a motivational strategy called contingency contracting. The target self-care behaviors are *appointment keeping*, and *maintenance of nutritional status*, two critical issues confronted by this patient population. A model of nursing care in head and neck cancer developed by the principal investigator, derived from Orem's Self-Care Deficit Theory, has guided the development of the interventions, the choice of study variables, and the prediction of outcomes.

Methodology—Adult head and neck cancer patients who are scheduled to receive either radiation or chemotherapy are stratified by treatment modality and gender; patients scheduled to receive both radiation and chemotherapy are stratified, on a random basis, to only one of the modalities for this study, even though they are receiving both. Subjects are then randomly assigned to one of three arms of the study: Education Alone, Education with Contracting, or an untreated Standard Care control group.

Subjects in the two experimental groups participate in three nursing intervention sessions of about 30-45 minutes with a research nurse who is not part of the regular hospital/clinic staff. These sessions coincide with critical phases in patients' treatment programs: Pretreatment, Treatment Week 3, and Final Treatment Week for radiation therapy; Pretreatment, upon hospitalization for Second Course of chemotherapy, and during hospitalization for Final Course of chemotherapy. The protocols are sufficiently flexible to accommodate the variations in patients' treatment schedules. Each session involves the presentation of an 18-minute audiovisual tape appropriate to the treatment modality and phase of treatment. Each tape is designed to familiarize patients with immediately relevant information regarding their treatment regimen, its side effects, and strategies to manage those side effects. The audiovisual program is supplemented with written materials, especially the self-care information (SCI) cards which reinforce the critical information and provide additional specific self-care techniques. The SCI cards also alert patients to the critical signs and symptoms that might require the attention of a physician or nurse.

Patients randomized to Education with Contracting, in addition to receiving the educational program, also participate with the nurse in formulating action goals and

agreements to carry out specific self-care behaviors for which they receive a self-selected and agreed-upon reward to reinforce the desired behavior. If the desired outcomes represent a significant challenge to the subject, they are broken down into smaller, manageable increments with the reward system serving to sustain the motivation to achieve the long-range goal.

Outcome measures include amount and types of self-care behaviors; functional, nutritional, and emotional health status; missed appointments; and quality of life. These data are obtained by research assistants who are blind to the subject's treatment group. The measures include standardized self-report instruments and inter-

views, as well as questionnaires and observation schedules developed specifically for this study. Data analysis plans include analysis of variance and covariance, as well as multiple regression.

Preliminary Results—Accrual and retention of this often hard-to-follow patient population has been excellent, exceeding projected sample sizes. Preliminary data suggest that education enhances patients' knowledge, but not necessarily the desired health behaviors, while the addition of contingency contracting results in increased action. It is too early to assess the statistical significance of these findings or to project the long-range outcomes of health status and quality of life.

[348] Living with Homecare: Cancer Patients and Their Caregivers

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—Recent efforts at cost containment have contributed to a shift from hospitalizing cancer patients who are receiving radiation therapy, to offering these services on an outpatient basis. With the shift to home care comes a number of problems. Little documentation exists on the health care service utilization patterns of cancer patients living at home, the extent to which existing services and insurance coverage meets their needs, their levels of satisfaction with services, their health care expenses, and the impact of outpatient care on patients and their families.

Methodology—Adult cancer patients who are undergoing radiation therapy are recruited into the study. Criteria for entry include: age 30 years or older, high likelihood of ongoing care needs related to cancer and cancer treatment, life expectancy of at least one year, and non-institutional residence. Patients (and their primary caregivers) are interviewed three times at 4-month intervals. Major variables include demographic data, physical

health and functional status, psychosocial variables such as measures of depression, stress, optimism, and social support, the need for home care and other services, and the costs of medical care incurred by the patients and caregivers. Caregivers are asked about the amounts of stress and burden they experience, as well as their needs for medical and home care services for the patient. Medical records are examined to collect information on diagnosis, type and site of cancer, prior therapy and outcomes, medications prescribed, and changes in health care status. Home health charts will be examined to extract information on the utilization and efficacy of these services. Agencies providing services to the patients will be contacted to collect information on costs and service utilization.

Future Plans—The study is currently in its final stages of recruitment and is scheduled to continue through January 1992. Preliminary analyses were begun in October 1990, upon completion of subject recruitment.

[349] Nurse Interventions Promoting Self-Help Response to Cancer

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—The purpose of this study is to: 1) determine the efficacy of promoting patient self-care during cancer treatment for women having a diagnosis of breast cancer through nurse interventions that provide information, enhance patients' ability to use the information, and/or support uncertainty-management interpretations of illness-related events; 2) describe person, disease, contextual factors, and time as variables that enhance or limit self-care activities during and following breast cancer treatment; and, 3) describe the efficiency of a model of nursing care for women with breast cancer within a health maintenance organization (HMO), a tertiary treatment center (Cancer Center), and within private practice sites.

Methodology—The 3×2×2 randomized block, repeated-measure design includes three analysis components: 1) a multivariate experimental analysis of nurse intervention, effect, and durability relative to four outcomes (self-care, self-help, life quality, and morbidity); 2) covariance analysis and multiple regression/correlation analysis of effects on the learned process of self-help during cancer experience that include testing the influence of concomitant variables grouped into person, disease, and contextual categories, and of time; and, 3) a cost-effectiveness analysis of a program of nursing care offered to selected cancer patients with an HMO, a Cancer Center, or a private physician care setting.

Progress—The study is in its second year of funding with more than 100 subjects having agreed thus far to participate in the full study. Thirty subjects participated in the pilot study. The Focus Group pre-pilot study informed specific content to be included in the self-help classes and in the initial case management contacts. A DBase formatted assessment tool has been developed for the case managers to provide a computer screen reference of

patient-specific information that can be used and then added to at the time of phone contact. The program provides a protocol for uncertainty management in a variety of situations. The protocols for the six self-help classes are available in a teacher's manual. Subjects participating in the self-help classes and in the independent study receive a workbook containing materials for six sessions. All materials are evaluated by the subjects.

The mean age of subjects on the pilot (P) and the first 50 cases from the full study (FS) is 54.4 years. Most of the women in both samples are married (P = 65%; FS = 72%). The samples are predominantly Anglo (P = 87%; FS = 92%), with a high level of education (P = 70% with some college or more; FS = 56% with some college or more), and an average income of \$26,000. Nearly half of each sample work either part-time or full time with half of those in the full study indicating they have taken a medical leave during cancer treatment.

Sixty-two percent of the full study sample stated they were diagnosed following the finding of a lump during a breast self-exam, 18% were diagnosed following a positive mammogram, and 6% were diagnosed following discovery of a lump during a physician exam. Sixty-eight percent promptly sought diagnosis and treatment, 6% said they delayed seeking diagnosis and/or treatment help, 24% said their physician promptly sought diagnosis and treatment, 5% said their physician delayed diagnosis and treatment, and 5% said treatment was delayed for other reasons. The discovery of delay of treatment categories was made during the pilot phase of the study when data collectors asked for information about the woman's diagnosis experience.

Recent Publications Resulting from This Research

A Self-Help Intervention Project (SHIP) in Breast Cancer Treatment.
Braden CJ et al., *Innovations Oncol Nurs* VI(2):1, 1990.

[350] Compact Disk-Interactive (CD-I) Tutorial and Simulation in Cancer Pain Management

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—The objectives of this project are to: 1) explore the use of compact disk-interactive (CD-I) multimedia technology for health-care education; 2) design a prototype instructional program for the education of physicians and nurses in cancer pain management; and, 3) evaluate the program's effectiveness for imparting information.

Methodology—Research activities began with assessment of entry-level knowledge of target audiences, determination of appropriate performance requirements, specification of instructional objectives for each content area and a detailed content outline, identification of materials for reference in content research, determination of media treatment indicated by the nature of the material, and prioritization of all educational and performance requirements. The result of this effort was the creation of an Instructional Analysis Document which served as the foundation of the instructional design. A variety of documents were developed (e.g., appropriate scripts, story boards, flowcharts, etc.), which became the "blueprint" for the CD-I program.

Results—Testing of the CD-I prototype program, developed between September 1989 and February 1990, was done in the clinical setting of the San Diego Hospice, where six subjects—all health care personnel responsible for caring for terminally ill cancer patients—each spent approximately one hour using and evaluating the program, then completing a two-page questionnaire. Subjects gave highest marks to the media approach, which they found to be clearer and more informative than a

nonmedia treatment. Most said that they enjoyed the exposure to new information. Subjects disliked the malfunctions in CD-I equipment and the occasional slowness of program response. All but one subject found the program easy to operate, and subjects overwhelmingly rated CD-I more effective as learning programs than textbooks, audio cassettes, or video cassettes. Half of the subjects rated CD-I more effective than classroom instruction.

Even in a very limited prototype, CD-I technology was proven effective in delivering information to the target population. No interactive design strategy was rejected on the grounds that CD-I technology was incapable of handling it. Aside from disk-mastering problems, software development proceeded in a reasonable time frame, and no other significant production problems arose. A large amount of interactive material was developed at minimal production cost and with minimal production facilities, and it was not difficult to correct or revise any of the content materials when errors were found.

Implications—Due to its ability to customize an educational presentation to the skills and interests of each individual student, interactive multimedia has long been known as one of the most effective learning technologies. Its usefulness, however, has been limited by its high price (\$4,000 to \$10,000 per system). CD-I technology will be available to educators in 1991 for \$750 per system or less. Its single-unit design, modeled after the audio compact disk player, makes it cost-effective, portable, and simple to operate. This technology promises to make interactive learning systems a standard item in the health care facility of the 1990s.

[351] Clinical Studies in Cancer Surgery/Cancer Rehabilitation

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—The Surgery Branch of the National Cancer Institute has a variety of studies investigating innovative therapies for patients with malignant diseases. The major

emphasis of these studies is in the treatment of soft tissue sarcomas, osteogenic sarcomas, colorectal cancer gastric cancer, renal cell cancer, and melanoma.

Postsurgical tissue and limb salvaging techniques are a critical part of the reconstructive process for the superior functional outcome of the patient. Medical rehabilitation research in this project is focused on the continued development and improvement of reconstructive processes, plastic surgery, postoperative X-ray and drug therapy, design of

endoprostheses, and refinement of psychosocial therapies. In addition, in soft tissue and osteogenic sarcomas, the focus on refinement of endoprostheses provides improvements in the body's response to their use in reconstructive procedures.

[352] Electrical Current in the Treatment of Malignant Tumors

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Sponsor: Republic Ministry for Research Activity and Technology of Slovenia, Yugoslavia

Purpose—The objective was to observe the effect of externally applied low level direct current (DC) on murine fibrosarcoma tumor model, and to investigate the possibility of enhancing antitumor effect of interferon alpha (IFN- α) by the application of DC.

Methodology—Antitumor effect of low level DC (0.6 mA) for 15 minutes per day, on 9 consecutive days, was tested on subcutaneous fibrosarcoma (Sa-1) in inbred A/J mice. Stainless steel electrodes, anode inserted directly into the tumor, cathode inserted subcutaneously caudally in the tumor vicinity, were employed. Treatment was started after the tumors reached approximately 50 mm³.

Combined treatment was carried out with partially purified human leukocyte IFN- α (5×10^4 I.U.) injected peritoneally prior to electrotherapy (ET) for 6 consecutive days.

Results—The antitumor effect of DC was observed 3 days after the beginning of ET, resulting in a tumor growth delay of approximately 1.5 days. IFN- α itself was as effective as ET.

Combined treatment was already found to be effective 24 hours after the beginning of treatment, and remained effective throughout the treatment period. It was more effective than IFN- α treatment alone, but not significantly more than ET itself.

Future Plans—The results indicate that ET does have an antitumor effect, therefore further work is required to optimize the treatment schedule with different current levels, polarity, and duration of treatment. The combined treatment results indicate that ET in combination with other biological response modifiers or cytotoxic agents can prove more effective.

Recent Publications Resulting from This Research

- Antitumor Effect of Human Leukocyte Interferon Alpha and Low Level Direct Current on Murine Sarcoma. Sersa G et al., J Cancer Res Clin Oncol 116 (Part I):S308, 1990.
- Low Intensity Direct Current as an Antitumor Agent? Miklavcic D et al., Radiologia Iugoslavica 24:75-78, 1990.
- Low Intensity Direct Current as an Antitumor Agent: A Preliminary Report. Miklavcic D et al., J Cancer Res Clin Oncol 116 (Part I):S587, 1990.
- Inhibition of SA-1 Tumor Growth in Mice by Human Leukocyte Interferon Alpha Combined with Low-Level Direct Current. Sersa G, Miklavcic D, Molecular Biotherapy (in press).

XI. Orthopedic Implants

For additional information on topics related to this category see the following Progress Reports: [74], [334], [335].

A. General

[353] Percutaneous Prosthetic Limb Attachment

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Sponsor: VA Rehabilitation Research and Development Service (Project #A487-RA)

Purpose—This project was initiated in order to develop a method for the attachment of prosthetic limbs to veteran amputees without the necessity of fitting the anatomy of the residual stump and incurring the inherent functional and cost limitations of current prosthetic practices. Utilization of residual muscle capability through a percutaneous implant is an ultimate goal.

A sheep model was chosen for initial investigations because of prior work in Spanish goats and because of the extensive use of sheep for bone-healing research.

Progress—An initial conception of the requirements of a transitional zone from internal to external milieu in order to eliminate infection led to the development of microvascular techniques for free vascularized transplant of small bowel, omentum, or parietal peritoneum to the site of a midtibial amputation. A four-fluted, self-tapping, stainless steel intramedullary device with a percutaneous pylon for prosthetic attachment was designed and implanted with transplant of tissue with the potential for reducing infection. This led to a classical osteomyelitis with extrusion of the implant and failure in 25 cases.

The implant was revised to a flat broach to preserve the endosteal blood supply and while the periosteal reaction and osteomyelitis developed more slowly and to a lesser extent in five cases, the outcome was, qualitatively, the same.

A review of the literature regarding mandibular implants led to exploration of the use of hydroxylapatite coating of the implant (without free vascularized transplants to establish a baseline of bone and tissue reaction). The initial results are qualitatively different from any

previous experience. The animals are healthier, they bear weight more readily, there is less drainage from the amputation site, fractures heal, and preliminary histologic data reveal new bone in close approximation to the implant. There is no apparent osteomyelitis at 2 months (previously readily apparent) and the skin appears to grow tightly around the stem of the implant.

Methodology—The sheep were acclimatized to the facility for 72 hours prior to surgery. Food was withheld for 48 hours and water for 24 hours. Preoperative sedation was with ketamine 1.5 g intramuscular. Induction for intubation was accomplished with 500 mg of intravenous, short-acting barbiturate and the anesthetic agent was Fluothane 1.5–2.5% with 4–5 liters of oxygen.

After routine clipping, without shaving, and skin preparation with iodine, tibial amputation at the isthmus was accomplished by a guillotine technique at a level distal to the final site. The periosteum was reflected from the distal shaft before amputation of the bone at the isthmus so that it could be reflected over the cut end of the bone into a recess in the implant.

A number of 316 L stainless steel implant broach sizes from 8 to 13 mm were precoated with hydroxylapatite by a plasma spray technique and sterilized with ethylene oxide. The maximum diameter of the tibia at the amputation site was measured and the next size larger implant was driven into the intramedullary canal without preliminary preparation.

Tendons were resected at the amputation level and the skin was closed tightly around the stem of the implant in contact with the hydroxylapatite coating. A simple

pylon prosthesis was friction-coupled to the stem of the implant. Aminoglycoside and cephalosporin were injected intramuscular at the end of the procedure and the animals were placed in a sling for 3 weeks.

Results—Three of five animals were walking with some weightbearing at 60 days. One animal has broken the prosthesis three times.

One animal fractured the distal tibia in the sling and did not heal.

One animal broke the implant at 5 weeks and was necropsied. There was firm fixation of the proximal stem

of the implant in the endosteal canal and ground section of the implant plus bone revealed very close approximation of new bone to coating. There was no evidence of infection.

Future Plans/Implications—The long-term history of these implants must still be evaluated, the prosthesis must be revised to tolerate the increased use imposed by a successful interface, and the possibility of attachment of the residual muscles and tendons to the prosthesis, through the implant, must be investigated.

[354] Fracture Healing and Bone Remodeling in Plated Long-Bones

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Sponsor: VA Rehabilitation Research and Development Service (Project #A294-2RA)

Purpose—The objectives of this study are to develop models of the fracture-healing process for both conservatively treated and internally plated longbone fractures.

Methodology—Both mathematical and experimental models of fracture healing are used to study the fracture healing process. The mathematical models utilize the finite element technique. Models of conservatively treated long-bone fractures and plated long-bone fractures have been developed. An osteogenic index is used to predict the regions of a fracture callus which will ossify first.

Laboratory models will be used to assess the efficacy of using shortened screws at the outer screw locations compared with using full-length screws for plated fractures. A strain gauge based torque-measuring screwdriver has been designed to monitor the insertion and removal torque of the screws which attach the fixation plate to the bone.

Results—Finite element models of plated long-bones show that slippage between the plate and the bone influences to a great extent the amount of stress shielding. Plate slippage is a direct function of screw tightness. A time-dependent, incremental remodeling program has been developed to predict the changes in density distribution caused by the implantation of orthopedic implants. Preliminary models of nonplated long-bones subjected to bending, axial, and torsional loads have been analyzed.

In the experimental phase of the study, plates have been applied to phenolic tubes modeling the human

radius. The use of unicortical end screws results in a plated bone construct that is 40% stronger in the bending-open loading mode, and 10% weaker in the bending-closed loading mode.

Future Plans/Implications—Future plans include the use of the strain gauge based screwdriver in surgery to compare insertion and removal torques of plated forearm fractures. It is anticipated that low values of removal torque will indicate that stress shielding is minimal and the risk of refracture will be low. The use of an incremental remodeling program will allow the prediction of changes in the density distribution caused by plate fixation.

Recent Publications Resulting from This Research

A Bone Surface Area Controlled Time-Dependent Theory for Remodeling (Abstract). Beaupre GS et al., Transactions of the Orthopedic Research Society, 14:311, 1989.

Fracture Healing Patterns Calculated from Stress Analyses of Bone Loading Histories (Abstract). Blenman PR, Carter DR, Beaupre GS, Transactions of the Orthopedic Research Society, 14:469, 1989.

The Role of Mechanical Loading in the Progressive Ossification of a Fracture Callus. Blenman PR, Carter DR, Beaupre GS, J Orthop Res 7:398407, 1989.

An Approach for Time-Dependent Bone Modeling and Remodeling—Application: A Preliminary Remodeling Simulation. Beaupre GS, Orr TE, Carter DR, J Orthop Res 8:662-670, 1990.

An Approach for Time-Dependent Bone Modeling and Remodeling—Theoretical Development. Beaupre GS, Orr TE, Carter DR, J Orthop Res 8:651-661, 1990.

Mechanical Stress Histories and Connective Tissue Differentiation (Abstract). Carter DR et al., First World Congress of Biomechanics, II:80, 1990.

Numerical Methods for Emulating Stress-Induced Remodeling in the Femur (Abstract). Beaupre GS, Orr TE, Carter DR, First World Congress of Biomechanics, II:200, 1990.

[355] Bone Ingrowth and Remodeling with Porous Coated Implants

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Sponsor: VA Rehabilitation Research and Development Service (Project #A501-RA)

Purpose—The purpose of this work is to formulate a comprehensive theory consistent with many features of skeletal growth and development, maintenance, regeneration, and degeneration. The results of our previous investigations indicate that tissue stress histories play a major role in regulating the biology of skeletal tissues, and that these influences are stronger and appear earlier in skeletal development than has been previously thought. The equations used to predict cartilage, bone, and mesenchymal tissue biology are similar to those that account for mechanical energy dissipation or the accumulation of fatigue damage in all materials. Our results may thus reflect fundamental characteristics of the transduction of mechanical energy to chemical energy in living organisms. The context in which this work is being conducted is porous coated/bony ingrowth prosthetic replacement of the proximal femur and tibia. The end product of this research will be a consistent framework of computer analyses which can be applied to predict the biological events associated with initial ingrowth and subsequent bone remodeling. We anticipate that it will be possible to apply these approaches to the design and evaluation of any implant in the body.

Methodology—In the course of our investigations, we will generate three-dimensional finite element models of the proximal femur and proximal tibia. The loading history over some period (e.g., an "average" day) will be specified by a series of discrete load cases applied for a specific number of load cycles. The entire bone will be represented initially by a solid, homogeneous structure with a constant bone density. Using a time-incremental bone remodeling technique, we will remodel the bone computer models to create an internal distribution of bone density and morphology which conforms to our bone remodeling theory. The resulting prediction of bone density distributions will be compared to those measured from cadaveric specimens. Our theory and computer approaches may then be modified so that our predictions correlate better with normal bone anatomy.

The proximal tibia and femur models will then be altered to represent the initial implantation of various uncemented porous coated components. A thin layer of pluripotential tissue will be represented at the bone/prosthesis interface. The multiple loading, stress history approach will then be applied and the differentiation of the interface tissue will be predicted. Using different stress history criteria, we will thus predict the extent and locations of bone ingrowth along the interfaces. Our criteria will be adjusted and varied parametrically to represent the types of results which have been observed by others in experimental animal studies and clinical retrievals. Subsequent bone remodeling around the prostheses will be calculated using the same algorithms which had been previously verified for the normal tibia and femur.

It is apparent that some design features may provide good initial fixation and encourage bone ingrowth, yet lead to subsequent bone remodeling which is deleterious. We will be able to address this issue with computer methods and thereby achieve a broad perspective of the overall implications of various design features. We anticipate that from the analyses that we perform, certain design features will begin to emerge which will suggest the evolution of cogent design principles for bony ingrowth total joint replacement. The proposed work represents a melding of basic and applied research. Our theoretical approach to the regulation of skeletal tissue by mechanical stresses will be explored and refined while it is being applied to solve immediate design problems which have a direct clinical impact.

Recent Publications Resulting from This Research

- A Bone Surface Area Controlled Time-Dependent Theory for Remodeling (Abstract). Beaupre GS et al., Transactions of the Orthopedic Research Society, 14:311, 1989.
- Femoral Bone Architecture Computed from 3-D Models Relating Bone Remodeling to Stress Histories (Abstract). Orr TE, Beaupre GS, Carter DR, in Proceedings of the XII International Congress of Biomechanics, 167, 1989.

Mechanical Stresses in Skeletal Morphogenesis and Maintenance (Abstract). Carter DR et al., in *Tissue Engineering* 1989, BED-14:55-58, S.L-Y. Woo, Y. Seguchi (Eds.). New York: ASME, 1989.

An Approach for Time-Dependent Bone Modeling and Remodeling—Application: A Preliminary Remodeling Simulation. Beaupre GS, Orr TE, Carter DR, *J Orthop Res* 8:662-670, 1990.

An Approach for Time-Dependent Bone Modeling and Remodeling—Theoretical Development. Beaupre GS, Orr TE, Carter DR, *J Orthop Res* 8:651-661, 1990.

Computer-Aided Implant Design Using Bone Remodeling Algorithms (Abstract). Orr TE, Beaupre GS, Carter DR, First World Congress of Biomechanics, II:192, 1990.

Computer Predictions of Bone Remodeling Around Porous-Coated Implants. Orr TE et al., *J Arthroplasty* 5(3), 1990.

Femoral Bone Architecture Computed from 3-D Models Relating Bone Remodeling to Stress Histories (Abstract). Orr TE, Beaupre GS, Carter DR, *Orthop Res Soc* 15:77, 1990.

Mechanical Stress Histories and Connective Tissue Differentiation (Abstract). Carter DR et al., First World Congress of Biomechanics, II:80, 1990.

Numerical Methods for Emulating Stress-Induced Remodeling in the Femur (Abstract). Beaupre GS, Orr TE, Carter DR, First World Congress of Biomechanics, II:200, 1990.

[356] High Viscosity Cooler Acrylic Bone Cement

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Sponsor: VA Rehabilitation Research and Development Service (Project #A143-3RA)

Purpose—The fundamental purpose of this work has been to identify methods to improve the fixation of prostheses to bone in order to reduce the rate of failure of cemented joint replacements, which are increasingly required in the aging VA patient population. The effort is even more important at present than originally in that cementless fixation of total joint prostheses, which was very prevalent in the mid-portion of the 1980s, has become less popular because of the frequency of intra-operative complications and a 20–30% incidence of postoperative thigh pain.

Methodology—Previously, we have shown that external pressure applied to polymerizing bone cement: 1) increases the shear strength of the cement itself; 2) increases the shear strength of the bone cement interface; and, 3) increases the penetration of cement into cancellous bone. Conversely, we have shown that increasing the depth of penetration: 1) does not result in an improvement in the shear strength of the bone-cement interface; and, 2) most recently in work just completed we have shown, *in vivo*, that the area of the interface fibrous membrane (an indicator of fixation failure) is directly related to the depth of cement penetration into bone.

With these observations in mind, we reasoned that the advantages of external pressure on the bone cement could be achieved without the disadvantage of excessive penetration by increasing the viscosity of the cement itself. This can be achieved by reducing the amount of monomer in the monomer/polymer mixture to increase the powder-to-liquid ratio. Although our primary intent

was to produce a high viscosity cement, we find that changing the standard powder-to-liquid ratio from 2.0 to 2.7 also affects other physical properties that should be beneficial to long-term fixation of implants. Specifically: 1) the strength in compression is increased; 2) the density is increased; and, 3) most importantly, the peak exotherm of the polymerizing composite is reduced by approximately 20 percent.

Currently, we are developing a delivery system that can be utilized in the clinical situation. Our canine and goat total-knee model had a short (2 cm) cannulated stem, and it was relatively easy to inject the high viscosity cement. For cemented hip replacement, retrograde injection of the femur requires a tube approximately 8 inches (20 cm) long. Since resistance to flow increases markedly with length, we had to design and fabricate a new delivery system. This has been accomplished by utilizing a hydraulic system that can be used to apply the concept of high viscosity cement in the clinical setting.

Future Plans—The delivery system works well in the laboratory, but before using it on humans we want to refine the technique and establish the concept *in vivo*, which is the primary thrust of our current work.

Recent Publications Resulting from This Research

A Comparison of Intramedullary Plugs Used in Total Hip Arthroplasty. Beim GM, Lavernia C, Convery FR, *J Arthroplasty* 4(2):139-141, 1989.

High Viscosity Acrylic Bone Cement. Hadjari M, Reindell ES, Convery FR, Transactions of the 36th Annual Meeting of the Orthopaedic Research Society, 29, 1990.

The Effects of Cement Penetration on the Bone-Cement Interface Membrane. Hadjari M et al., Transactions of the 36th Annual Meeting of the Orthopaedic Research Society, 439, 1990.

Cardiopulmonary Function During Canine Total Knee Replacement Using Sustained Pressurization of Bone Cement. Weiner GM et al., J Arthroplasty (accepted for publication).

[357] Effects of Treatment for Heterotopic Bone Formation on Biological Fixation

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Sponsor: VA Rehabilitation Research and Development Service (Project #A450-RA)

Purpose—The purpose of this study is to evaluate the effects of several short-term and chronic indomethacin therapies on the amount of bone growth into a porous surface and the bone-implant attachment strength.

Ectopic ossification following total hip arthroplasty is a frequently reported complication. Treatments for the prevention of heterotopic bone have included diphosphonate, radiation, and indomethacin therapies. Clinically, indomethacin has been shown to be effective in reducing ectopic bone formation, and effective in preventing heterotopic bone formation induced by demineralized bone matrix. Chronic indomethacin may significantly reduce the amount of bone growth into a porous implant, as well as reduce the bone-implant attachment strength. Since indomethacin is also used as an anti-inflammatory drug in several patient groups, the question arises as to what duration and at what period postoperatively does indomethacin usage prohibit effective bone-porous implant attachment.

Methodology—The animal model used was the skeletally mature mongrel canine approximately 18 to 22 kg in weight. Cylindrical Ti-6Al-4V alloy implants, 5.1mm in diameter by either 18mm or 20mm length, were coated with a two-layer spherical bead Ti-6Al-4V alloy porous coating. The implants were placed in the femoral bone through both cortices using strict aseptic techniques; each animal received 5 to 6 implants bilaterally.

Animals were randomly assigned to the following groups: 1) *Controls*—no drugs; 2) *Chronic*—indomethacin daily for 2 weeks preoperative until sacrifice; 3) *Heterotopic*—indomethacin immediately postoperative continued daily for 6 weeks; 4) *3-week delay*—indomethacin daily beginning 3 weeks postoperative until sacrifice; 5) *6-week delay*—indomethacin daily beginning 6 weeks postoperative until sacrifice; 6) *9-week delay*—indomethacin daily beginning 9 weeks postoperative until

sacrifice; and, 7) *18-week delay*—indomethacin daily beginning 18 weeks postoperative until sacrifice. Implantation periods included 3, 6, 12, 18, and 24 weeks. This experimental design resulted in 26 treatments (combinations of drug/implantation time) to be evaluated.

All animals (except controls) received 1.0mm/kg/day of indomethacin orally in two divided doses. Blood was drawn at regular intervals during therapy to confirm blood/indomethacin levels.

After sacrifice, the implants were harvested and subjected to mechanical push-out testing to determine interface attachment strength. The resulting data was analyzed separately to examine the effects of implantation time and drug treatment groups.

Intact and tested samples were evaluated using standard undecalcified histologic techniques. The evaluations were based on qualitative gradings of mineralization and osteoid formation, and computerized quantitative percent bone ingrowth measurements.

Results—For each of the seven drug treatments there was a significant effect of time of implantation upon shear strength (all $p < 0.0025$) as follows: *Control* group—significant increase in strength from 6 to 12 to 18 weeks; *Heterotopic* indomethacin group—average strengths significantly lower at 6 weeks as compared to 12 and 18 weeks; *Chronic* indomethacin group—strength data increased significantly from 3 to 6 to 24 weeks. Strengths for animals receiving indomethacin after a 3-, 6-, or 9-week delay were significantly greater at the 24-week interval.

Evaluation of the strength data after 6 weeks demonstrated a significant drug group effect ($p < 0.05$), with the strength values for the *Chronic* indomethacin group significantly greater than the *Control* and *Heterotopic* groups. Similar results were observed at the 24-week time period, with the strengths for the *Chronic* in

domethacin group significantly greater than the 3-, 6-, 9-, and 18-week delay groups. After 12 and 18 weeks implantation, there were no significant differences in strength among the drug groups ($p=0.25$).

Implications—These results indicate that indomethacin given strictly postoperatively has no consistent detrimental effect upon fixation strength. It was unexpected that animals receiving chronic indomethacin would exhibit greater strength values; perhaps a longer preoperative therapy would have altered these findings. While the effect of indomethacin given strictly postoperatively

remains unclear, strengths appear to be unaffected by a delay of 6 weeks or longer.

Recent Publications Resulting from This Research

Effects of Treatments for Heterotopic Bone Formation on Biologic Ingrowth Fixation. Thomas KA, Cook SD, Brinker MR, Digest of Papers Eighth Southern Biomedical Engineering Conference, Richmond, VA, 1989. (Abstract published in *Biomater Artif Cells Artif Organs* 17:515, 1989.)

Effects of Indomethacin on Biologic Ingrowth Fixation. Poster exhibit, 16th Annual Meeting of the Society for Biomaterials, Charleston, SC, 1990. (Abstract published in *Transactions*, XIII:231, 1990.)

[358] Effect of Surgical Fit on the Biological and Mechanical Response to Porous-Surfaced Implants

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Sponsor: VA Rehabilitation Research and Development Service (Project #A136-3RA)

Purpose—The purpose of this study is to investigate the effects of a uniform gap space between a porous implant and surrounding bone on the degree and maturity of bone growth into the porous surface, and to determine the effect of the gap upon interface attachment strength. The implant design assures the presence of uniform gap spaces of varying sizes between the implant surface and the surrounding bone, and also allows for evaluation in regions of cortical and cancellous bone.

Ideally, a porous-surfaced implant relying on bone ingrowth fixation should make initial apposition with the surrounding bone. Unfortunately, this is not always achieved surgically at all locations and a space between the implant and bone is present. This space may be the result of deficiencies in instrumentation design, implant design, or surgical technique. The gap may severely alter the type, amount, and rate at which tissue infiltrates the porous-implant surface. Thus, the development of significant fixation strength may be delayed and the ultimate attachment strength adversely affected.

Methodology—Femoral intramedullary implants were constructed by threading Ti-6Al-4V alloy porous coated discs of 6.0, 8.0, 9.0, and 10.0mm diameters onto a central 2mm threaded rod. Each implant consisted of four 4.0mm thick discs of each diameter, separated by solid acrylic spacers 10.0mm in diameter and approximately 2.0mm thick. The assembled implants were approxi-

mately 100.0mm long. Three different disc arrangements were used for each time period, allowing two discs of each diameter to reside in the cancellous (metaphyseal) region and the cortical (diaphyseal) region of the femur.

The animal model was the skeletally mature mongrel canine ranging in weight from approximately 18 to 22kg. Identical implants were inserted bilaterally into the femoral intramedullary canal using standard aseptic techniques. Five animals at each implantation period (4, 8, 12, 24, and 52 weeks) were randomly assigned one of three implant arrangements.

Harvested femurs were sectioned by cutting through the acrylic spacers to produce individual test specimens. These specimens were mechanically tested with a specially designed push-out fixture to determine interface shear attachment strength.

Future Plans/Implications—Both tested and intact specimens will be processed using undecalcified techniques to produce histologic and microradiographic sections for evaluation. The amount of maturing bone growth in apposition to and within the porous surface, as well as the amount of gap filling will be quantified on all histologic specimens. The data will be analyzed to determine differences among the implants in cortical and cancellous bone regions as well as any differences in medial, lateral, posterior, or anterior locations.

This study will determine the limits of the ability of new bone growth to fill a gap space at various time periods. The effects of bone ingrowth and gap filling upon the resultant interface attachment strength will also be determined,

as well as evaluating how the response may differ between cortical and cancellous bone. This information will help answer many questions critical to the design and use of noncemented porous-coated devices in the clinical setting.

[359] Optimization of Orderly Oriented Wire Mesh for Prosthetic Arthroplasty

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Sponsor: VA Rehabilitation Research and Development Service (Project #A356-2RA)

Purpose—Orderly oriented wire mesh (OOWM) is a pure titanium porous coating which represents a unique approach to the biologic fixation of hip or knee implants. Prior work supported the utility of the material for biologic fixation of implants in a canine model. This study seeks to optimize the performance of material through the use of both *in vivo* and *in vitro* models.

Methodology—Three hypotheses will be studied: 1) that optimization of the geometry of the mesh-substrate interface will minimize the reduction in fatigue strength of the sintered implant; 2) that biologic fixation of the OOWM can be optimized by appropriate manipulation of the dimensions of the mesh wires and weave; and, 3) that OOWM-coated prostheses will offer enhanced fixation of the implant to PMMA bone cement, without compromising cement fatigue and static properties.

The first hypothesis will be investigated through development of a two-dimensional finite element model of the stress concentration (K_t) at the sinterneck interface.

The optimized K_t developed from this model will then be validated through the mechanical testing of a range of sinterneck radii to validate the results of the FEA model. This will then allow the design of an OOWM that should minimize reduction in fatigue strength over traditional sintered surfaces.

The second hypothesis will be investigated using *in vivo* analysis of pull-out resistance of implants with pore structures different in size from that already investigated, in an attempt to optimize the strength of biologic fixation of OOWM-coated implants. Two additional OOWMs with substantially different pore sizes will be investigated.

The third hypothesis will examine the fatigue strength of the OOWM-PMMA cement interface, in an effort to demonstrate enhancement of cement implant shear and fatigue performance compared with uncoated implants. This will require *in vitro* mechanical testing and fractographic analysis in order to validate the use of OOWM for cemented implants.

[360] Evaluation and Examination of Retrieved Porous-Coated Orthopaedic Prostheses

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Purpose—The overall objective of this study is to assess the long-term feasibility of porous coating as a mechanism for fixing orthopaedic prostheses to bone.

This examination of clinically retrieved, porous-coated hip and knee prostheses will assess the importance of such variables as material composition (cobalt and titanium-based alloy systems), design (implant geometry),

location of porous coating on the prosthesis, coating pore size, pore geometry, pore density, and surface roughness on the resulting interface between the prosthesis and bone. The study will address the issues of stress shielding, ion release and wear debris formation, and, where possible, clarify causal relationships with prosthesis parameters.

Methodology—Retrieved prostheses are fixed in formalin for 48 hours, examined macroscopically for both soft and hard tissue apposition to the prosthesis and mapped for the location of this tissue. The prosthesis is coarsely sectioned and the large sections are dried in a series of alcohol and acetone solutions. Fully dried prosthetic components are embedded in ethyl-methacrylate and cut into sections approximately 1 mm thick. These sections are hand-ground to between 20 and 40 μ in thickness and hand polished. Specimens are stained with either hematoxylin and eosin (H and E) or acid phosphatase, cover-glassed and photographed on a Zeiss photomicroscope III. The interface is mapped and evaluated for bone and fibrous tissue ingrowth, osteoblastic and bone resorptive activity, and the presence of polyethylene or metal wear debris.

Results—In the past 12 months, we have examined 378 retrieved, porous-coated orthopaedic prostheses. This compares favorably with the 249 prostheses examined in the first year of this project. One hundred and ninety-five hip prostheses were received from 85 surgeons; 183 knee prostheses were received from 48 surgeons. Eighteen of the 378 prostheses were retrieved post mortem from cadaver specimens.

Bone ingrowth of large and small pore sizes of both titanium and cobalt alloy was demonstrated. The amount extent of bone ingrowth was found to be a function of implantation duration and implant design and fixation mechanisms.

Bone ingrowth of femoral hip prostheses, femoral knee prostheses, and patellar prostheses was frequently seen. Bone ingrowth of acetabular prostheses was much less frequently seen; bone ingrowth of tibial prostheses was seen least frequently of those device types evaluated. Tibial prostheses with porous-coated central pegs demonstrated bone ingrowth of the central peg more frequently than ingrowth of the porous-coated plateau. The most frequent bone ingrowth of the underside of the tibial plateau was seen with prostheses fixed with four metal screws. Generally, there was evidence of metal fretting between the screws and the screw holes and the local tissue had often turned black. Metal ion concentrations in this tissue was measured as greater than 1% by weight in several cases.

Worn polyethylene articular surfaces and the development of significant amounts of polyethylene wear debris was seen in a high percentage of knee prostheses.

Mechanisms of failure of patellar and tibial components included: separation of polyethylene from the metal backing, wear-through of the polyethylene, cracking, pitting, and delamination of the articulating surface, as well as deformation of the polymer due to creep. Examination of the ingrowth surfaces of tibial and patellar prostheses which had been retrieved for reasons of polyethylene failure often demonstrated polyethylene wear debris at the margins of the porous coating which appears to be associated with localized osteoclastic activity and bone resorption.

Several surprising phenomena not previously reported were documented through the prosthesis examination process this year. These included: 1) the deformation and high wear rate of the thin polyethylene inserts used in metal-backed acetabular components; 2) the considerable wear of titanium heads used in femoral hip prostheses; 3) corrosion at the interface between cobalt alloy heads and titanium alloy femoral hip stems; 4) separation of bone-ingrown titanium wire mesh pads from the substrate of femoral hip prostheses; and, 5) the loss of material from some plasma-sprayed and sintered bead porous coatings that migrated to the articular surfaces resulting in early failure of the polyethylene and significant wear of the metal components.

Recent Publications Resulting from This Research

- The Case for Pressfit Femoral Stem Fixation. McCutchen JW, Collier JP, presented at the 18th Open Scientific Meeting of The Hip Society, New Orleans, 1990.
- Early Failure of Polyethylene Components in Uncemented Total Knees. Surprenant VA et al., presented at the 57th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, 1990.
- Examination of Porous-Coated Patellar Components and Analysis of the Reasons for Their Retrieval. Collier JP et al., presented at the 57th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, 1990.
- The Success of Pegs, Stems and Screws as Adjuvant Means of Fixation of Tibial Prostheses as Measured by Radiographic and Histological Examination. Collier JP et al., presented at the 57th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, 1990.
- Biological Ingrowth of Porous-Coated Knee Prostheses. Collier JP et al., in *Controversies of Total Knee Arthroplasty: Issues of the Nineties*. New York: Raven Press (in press).
- The Biomechanical Problems of Polyethylene as a Bearing Surface. Collier JP et al., *Clin Orthop Rel Res* (in press).
- The Case for Pressfit Femoral Stem Fixation. McCutchen JW, Collier JP, *Clin Orthop Rel Res* (in press).
- Corrosion at the Interface of Cobalt-Alloy Heads on Titanium-Alloy Stems. Collier JP et al., *J Bone Joint Surg* (in press).

[361] Surface Failure in UHMWPE Joint Components

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Purpose—The purpose of this research is to establish failure criteria for the articulating surfaces of ultrahigh molecular weight polyethylene (UHMWPE) components used in total joint replacement systems, and to apply these criteria to optimize implant design. Observations of retrieved components have revealed distinct patterns of damage, apparently caused by fatigue fracture mechanisms. The design decisions for UHMWPE components are based on the assumption that particular stresses and stress distributions (i.e., the maximum shear stress and the range of maximum principal stress) are responsible for causing damage. To verify the direct relationship between specific stress states and the production of surface damage, the conditions under which growing fatigue cracks in UHMWPE will change direction must be established. Our goal is to determine the cyclic loading conditions which will cause small defects on and below the surface to propagate and create the observed damage. The approach is based upon principles of fracture mechanics.

Methodology—Test variables will be the angle of inclination of the crack relative to the direction of the applied loading and the state of preconditioning of the material under uniaxial cyclic loading prior to testing. Tests will be conducted on specimens made from both conventional UHMWPE and enhanced forms of UHMWPE. Empirical relationships will be used as input to a numerical model to demonstrate that the method correctly predicts fatigue crack propagation in UHMWPE. This will be accomplished by modeling the test specimen geometry and loading conditions from the fatigue tests and comparing the computed crack propagation rates and direction with those measured experimentally. If fatigue crack propagation in UHMWPE cannot be described on the basis of linear elastic fracture mechanics, the analytical method will be modified to include nonlinear material behavior around the crack tip.

Progress/Preliminary Results—Fatigue crack propagation resistance of enhanced polyethylene was determined to be isotropic and more resistant to crack propagation than conventional polyethylene. Preconditioning was found to affect crack failure properties. Extensive evaluations were made of various stresses produced in joint surface contact between the metal and polyethylene components. Complex stress

patterns were measured and predicted with finite element modeling. Maximum shear stress was located at a depth of 1 or 2 mm in tibial components. This compares favorably with the depth of pits and delaminations seen in these materials. Nonconforming surfaces in some modern knee joint designs (e.g., cruciate ligament sparing devices) have much larger stress on the components.

Future Plans/Implications—We plan to determine the relationship between the crack growth rate and the applied cyclic stress intensity. Previous work showed that this relationship is insensitive to standard processing techniques in the opening mode. This work will examine: 1) effects of mixed-mode loading conditions, under which the propagating crack could be expected to change direction, with the fatigue crack propagation rate and crack trajectory being a function of both the opening mode (Mode I) and sliding mode (Mode II) stress intensity factors; 2) effects of a new type of UHMWPE, made by a processing technique which alters the mechanical and physical properties, and can be expected to alter the fatigue crack propagation behavior beyond the inconsequential differences found previously between the extruded and molded versions of conventional UHMWPE; and, 3) effects of preconditioning or working the material, which will occur under the high intensity cyclic loads applied to the articulating surface of an implant prior to crack initiation, and which can be expected to affect the material properties and the fatigue crack propagation relationship for UHMWPE.

We will then use the empirical relationships in a two-dimensional, plane strain, numerical method based on linear elastic fracture mechanics and demonstrate that the numerical method correctly predicts fatigue crack propagation in UHMWPE by modeling the test specimen geometry and loading conditions from aim one and comparing the computed crack propagation rates and directions with those measured experimentally.

Recent Publications Resulting from This Research

The Effect of Waveform and Compressive Loading on the Fatigue Crack Propagation Behavior of UHMWPE. Rimnac CM, Wright TM, Klein RW, in Transactions of the 35th Orthopedic Research Society Meeting, 14:487, 1989.

[362] Cell Response to Modified Ti Surfaces (Rats)

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Purpose—Dental implants fabricated from titanium (Ti) and Ti-6Al-4V alloy are widely used in clinical practice, yet there is no consensus or established criterion regarding the design or fabrication of implant surfaces. As a result, there is little information currently available concerning specific biological responses, such as deposition of extracellular matrix molecules and attachment of cells, which occur during the initial stages of wound healing at the intimate implant and hard and soft tissue interfaces.

The overall objective of this research is to investigate some of the cell responses to standard, commercially available implant surfaces, as well as to modified Ti-based implant surfaces. Preliminary data from our lab suggest that available implant systems vary widely in surface topography and that molecular interactions and attachment of cells at these surfaces are affected by the nature of the substrate.

The experiments in this project are specifically designed to study a number of variables by surface characterization techniques, including scanning electron microscopy (SEM/EDAX), electron spectroscopy for chemical analysis (ESCA), auger electron spectroscopy (AES), and surface energy (contact angle) measurements. The effects of variables such as type of metal, surface topography, oxide structure and composition, and surface charge and energy on fundamental biological events (such as matrix adhesion, cellular attachment, and spreading

and proliferation on these surfaces) will be ascertained. We hypothesize that chemical and biochemical modifications of the implant surface will result in enhanced biological acceptance and long-term tissue integration.

Implications—This type of research has far-reaching clinical implications in that it will define a model implant surface which can foster improved tissue reactions, thereby potentially decreasing the long healing periods now necessary with most commercial implant systems.

Recent Publications Resulting from This Research

- Characterization of Acid Passivated cpTi Surfaces. Keller JC et al., J Dent Res 68:872, 1989.
- In Vitro Cell Attachment to Characterized cpTitanium Surfaces. Keller JC et al., J Adhesion 28:115-133, 1989.
- Surface Characteristics of Prepared cpTi Implants. Keller JC et al., Transactions of the First International Congress on Dental Materials, 271-272, 1989.
- Bacterial Adhesion to Titanium Surfaces: Development of an In Vitro Model. (Abstract) Patel M, Drake DR, Keller JC, J Dent Res 69:369, 1990.
- Development of a Model for Cell Attachment. (Abstract) Clavin TJ et al., J Dent Res 69:369, 1990.
- In Vitro PDL Fibroblast Attachment to Plasma Cleaned cpTi Surfaces. (Abstract) Michaels CM et al., J Dent Res 69:369, 1990.
- Protein Adsorption is Decreased on Glow Discharged Treated cpTi. (Abstract) Stanford CM et al., J Dent Res 69:369, 1990.
- Role of Integrin Receptors in Osteoblast Attachment to cpTi. Stanford CM, Keller JC, Solursh M, J Dent Res 69:109, 1990.

[363] Titanium and Ti-6Al-4V Alloy Implant Fabrication (Rabbits)

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Purpose—The long-term objective of this investigation is to use a new process, electro-discharge compaction, for custom designing porous titanium and titanium alloy implants and superstructures. The ultimate goal is to develop a method whereby tooth roots can be duplicated and the resulting implants can be placed in extraction sockets within 24 hours of extraction. This would minimize surgical complications and provide an inexpensive means for replacing teeth. The method should also

provide the mechanism for constructing superstructures for any titanium or titanium alloy implants to minimize corrosion.

Methodology—Preforms will be developed that will satisfy criteria for titanium and titanium alloy dental implants by varying energy input. This project will evaluate the surface characteristics of the preforms to determine the character of the surface, the oxide layer,

the chemical composition of the contaminants, pore size, and grain structure as the energy input is varied. When the preform technique is perfected and consistent results can be attained, the electro-discharge compaction method will be used to prepare preforms of titanium and

titanium alloys that can be used to evaluate the biocompatibility of the preforms fabricated with the new technique. Rabbits will be used to determine soft tissue and bone tissue compatibilities. Osseointegration capabilities will be determined.

[364] Ion Sputter Deposition of Ca-P Thin Films

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Sponsor: *National Science Foundation*

Purpose—The overall goal of this research project has been to coat metallic materials with biocompatible Ca-P ceramic materials using the ion-beam sputter deposition process. Most orthopedic and dental implants are constructed of metallic materials such as titanium or cobalt-based alloys. A number of ceramic materials containing calcium and phosphorus have found increasing use for biomedical applications due to their biocompatibility and ability to form a chemical bond with bone. However, these particular ceramics are brittle and are not suitable for use in load-bearing implant applications, so their optimum use for most medical and dental applications may be as coatings on metals.

Methodology—The ion-beam sputter coating process used in this study employs high velocity gas ions to dislodge atomic fragments of ceramic target materials, which in turn will coat metallic implants placed in the path of the sputtered material. For this study, three target materials have been used: a hydroxyapatite-fluorapatite (HA-FA) target, and two high phosphorus glass targets. The HA-FA target has a Ca/P ratio of 1.67, whereas Glass-I, a calcium metaphosphate glass with the chemical formula $\text{Ca}(\text{PO}_3)_2$, and Glass-II, a commercially obtained calcium phosphate glass (Glass-II) with a 2% silica addition, have a Ca/P ratio of 0.5. Titanium discs (1 cm diameter, 2 mm thick) were coated by sputtering each of the three targets. As the sputtered coatings are amorphous, heat treatments were employed to obtain crystalline phases in the coatings.

Results—The bond strengths and solubility of as-sputtered and heat-treated specimens have been evaluated. Bond strength of the coatings to the substrates were determined using the Sebastian V z-axis tensile bond tester. Reflected light microscopy was used to find the exact failure loca-

tion of each coated specimen. For the solubility studies, coated samples were exposed to a 0.9% NaCl solution for varying time periods after which the coatings were evaluated using SEM and EDS analyses.

In general, the as-sputtered coatings produced the highest bond strengths while the heat treatments significantly reduced the adhesion of the coatings. One exception was observed. The heat-treated coatings produced with Glass-II exhibited bond strengths as high as those observed for the as-sputtered coatings. For the solubility evaluations, all as-sputtered coatings dissolved within 1 to 3 hours after immersion in the saline solution. The heat-treated coatings produced with the HA-FA target remained after 6 weeks and thus had the lowest solubility. The heat-treated coatings produced with Glass-I and Glass-II targets dissolved within 1 to 4 days.

Future Plans—Additional efforts on this study will concentrate on the optimization of coating chemistry and structure. Coating chemistry will be controlled by the use of different ceramic targets such as: 1) glasses containing higher Ca content materials; and, 2) glass and ceramic targets containing F. By controlling the composition of these glass targets, a coating chemistry more similar to hydroxylapatite may be obtained. The structure of the coatings will be controlled by optimizing post deposition heat treatments used for the production of crystalline phases in the as-sputtered coatings. The use of vacuum and controlled atmosphere heat treatments will be investigated to determine if both high crystallinity and high bond strength of the Ca-P coatings can be achieved. The most important goal in next year's work is to maximize crystallinity as a means of reducing coating solubility while maintaining a sufficiently high bond strength of the coating to the metallic substrate.

Recent Publications Resulting from This Research

Characterization of an Ion-Beam Sputter Deposited Calcium Phosphate Coating. Rigney ED et al., International Association for Dental Research Program and Abstracts, 835, 1990.

The Effect of Heat Treatments of Ion-Beam Sputter Deposited Calcium Phosphate Coatings. Rigney ED et al., Transactions of the Sixteenth Annual Meeting of the Society for Biomaterials, 13, 1990.

ESCA Analysis of Passivated Titanium and Ca-P Surfaces. Harris JL et al., Transactions of the Sixteenth Annual Meeting of the Society for Biomaterials, 44, 1990.

The Optimization of Ca-P Ion-Sputtered Thin Films. Gantenberg B et al., International Association for Dental Research Program and Abstracts, 197, 1990.

[365] Ion Implantation to Reduce Wear on Polyethylene Prosthetic Devices

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Sponsor: *National Science Foundation*

Purpose—Spire Corporation is continuing its research in the surface modification of Ultra-High-Molecular-Weight-Polyethylene (UHMWPE) through the use of ion beam processing. The National Science Foundation (NSF) Phase I program was successful in identifying the ion beam processing parameters which can provide UHMWPE with increased microhardness and reduced coefficient of friction. The goal of the NSF Phase II effort, which commenced August 1, 1989, has been to investigate the modified surface properties of ion beam-processed UHMWPE. The treated UHMWPE will be studied in wear simulation against Ti-6Al-4V and Co-Cr alloys.

Methodology—Based on the preliminary results from the Phase I study, the Phase II effort concentrated on studying the wear performance of ion beam-processed UHMWPE in simulated wear environments. The Phase I program showed that ion implantation of various ion species into UHMWPE increased microhardness and reduced coefficient of friction. The ion beam parameters for this processing were established. In the Phase II program, ion-implanted UHMWPE test disks were tested against Ti-6Al-4V and Co-Cr alloy pins. The pin-on-disk apparatus was specially designed to enable testing in both Ringer's solution and bovine serum. Physiological loads were used in the testing. Test results showed a 60% reduction in polyethylene wear tracks and a marked reduction in the UHMWPE wear debris generation. Coefficient of friction measurements were also made during testing, and results showed a 15% improvement in both the Ringer's solution and bovine serum.

Results—Ongoing investigation has included studies of the relationship of the surface finish of the UHMWPE to the wear results. Initial findings indicated a strong inter-

relationship between surface finish and wear results. The effect of the vacuum environment during and after processing on the performance of the UHMWPE was also studied. Raman spectroscopy has been used to analyze the modified surface microstructure. Rutherford backscattering spectroscopy (RBS) is used as an additional analysis tool. RBS has shown a significant increase in carbon at the surface of the treated UHMWPE which indicates a densification of the near surface region. This phenomenon contributes to the improved properties of the material.

Future Plans—Based on the results of the Phase I and II studies, several large orthopedic firms have expressed considerable interest in applying the ion implantation process to the articulating surfaces of UHMWPE components of prosthetic devices. To date, our research has mainly been from a materials approach, while the orthopedic manufacturers must approach new processes with the goal of ultimate FDA approval and widespread use. For these reasons, they must address concerns such as biological response to the treated UHMWPE and potential harmful effects, if any. Additionally, since the marketing of orthopedic devices is a major consideration, the cosmetic implications of a "different" material must be assessed. These concerns are being studied in parallel with the NSF program in hopes of reducing the time to market.

Following the Phase II program, it is our goal to team up with an orthopedic manufacturer and test the ion beam-processed UHMWPE in knee and hip joint simulators.

Patents

Ion Implantation of Plastics. Patent Number: 4,743,493; Date of Patent: May 10, 1988.

Ion Implantation of Polyethylene Orthopedic Implants. Patent applied for: July 31, 1990.

B. Hip

[366] Epiphyseal Hip Replacement: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Pilot Project #B987-PA)

Purpose—Conventional total hip joint replacement is a highly successful surgical procedure for treatment of severe arthritis of the hip. However, the incidence of mechanical loosening and stem fracture has become an increasingly significant problem, especially in younger patients. This has renewed interest in conservative alternatives. One such alternative is our epiphyseal replacement prosthesis, a new research-based design which incorporates the interface contours suggested by the geometry of the epiphyseal plate or scar.

Methodology—Using engineering design and finite element analysis techniques, we have attempted to improve on the generic type of hip surface replacement by critical design changes which appear to be of major benefit on a theoretical basis.

Progress—During this 1-year pilot project, computer modeling and laboratory testing of a new epiphyseal hip surface replacement was completed. The results of the computer modeling are reported in the article listed below. The computer analyses used a state-of-the-art bone remodeling algorithm to simulate the bony adaptation caused by the presence of the prosthetic implant. As

a result of these bone remodeling simulations, initial design modifications could be made prior to implantations in animals or humans.

In conjunction with the computer modeling studies, a series of laboratory prototypes was also created. The prototypes were used to: 1) develop the necessary surgical instrumentation; and, 2) test different designs used for initial implant stability. The instrumentation consists of two reamers that are used sequentially to prepare the femoral head for prosthetic seating. A set of nine spikes (1.0 mm in diameter and 5 mm in length) is used to provide initial stability and to encourage bony ingrowth.

Due to unforeseen manufacturing difficulties, titanium prototype prostheses for the *in vivo* animal study have not yet been completed. Additional computer models and laboratory prototypes have been completed. Although it is not possible to obtain the precise time course of bone remodeling without the use of *in vivo* implantation, the computer simulations lend additional support for the efficacy of the epiphyseal replacement concept.

Recent Publications Resulting from This Research

Computer Predictions of Bone Remodeling Around Porous-Coated Implants. Orr TE et al., J Arthroplasty 5(3), 1990.

[367] Quantitative Analysis of Total Hip Arthroplasty on Stress and Strain

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Sponsor: VA Rehabilitation Research and Development Service (Project #A100-4RA)

Purpose—Total hip arthroplasty design continues to evolve as the need for long-term reconstruction performance enhancement persists. Assessment of new design features requires quantitative comparative data on the effect of both design and materials selection on the stresses and strains seen by the bone so that a biologically effective reconstruction can be affected.

Preliminary Results—Assessment of the overall strain distributions, using optical methods for strain assessments to replace strain gauges, has been carried out. This noncontact full-field assessment tool would be of great value in continued research in total joint replacement. Holographic interferometry (HI) allowed for the successful qualitative assessment. Finite element comparisons

correlated well with these preliminary results. In an effort to gain more quantitative information, speckle shearing interferometry (SSI), another optical method, has been utilized. It allows optical differentiation of displacement data so that errors of mathematical differentiation may be reduced. To date, a simplified cylindrical Plexiglas™ model of the femur has been tested. Theoretical predictions and finite element modeling and strain gauge data have correlated well. These results also show excellent reproducibility. Effective utilization of SSI, however, requires the development of computerized automated fringe interpretation methodologies to allow quantified analysis of the alteration of surface strain following prosthesis implantation. In addition, early work using SSI was applied to flat two-dimensional (2-D) objects. To validate our technique for three-dimensional (3-D) objects, a series of experiments has been carried out over the last year. Double exposure plates yielded data for analysis using a prototype computer system. Calibration of the prototype system of fringe analysis indicates $\pm 4\%$ accuracy. Defocusing led to significant errors. These problems were obviated by using f/stops that were smaller (increasing depth of field), and increasing exposure time.

Future Plans/Implications—The next step of the experiments will be to auto-acquire speckle data with a video camera system. This system allows electronic filtering of the frequency modulated speckle patterns, thus improving the fringe location and subsequent strain assessments. Development of these computerized assessment tools continues as cadaveric proximal femurs with implants are assessed. This will allow assessment of press-fit porous-coated devices with various geometric configurations, including “off the shelf” designs and custom prostheses, thus leading to quantitative information on the effects of these new implant designs on femoral bone strain in this immediate postoperative model.

Recent Publications Resulting from This Research

- Applied Optics in Biomechanics. Wheeler D, Chitsaz B, in Proceedings of the Photo-Mechanics Conference, Blacksburg, VA, 15-17, 1990.
- Biomechanical Assessment of “Screw-In” Metal-Backed Acetabular Prostheses. Miller GJ, Wheeler D, Petty RW, in Proceedings of 1st World Congress of Biomechanics, San Diego, 1990.
- Evaluation of Allograft Fixation. Vander Griend R, Sollaci C, Miller GJ, in Proceedings of 5th International Symposium on Limb Salvage Surgery (in press).
- Total Hip Replacement: Biomechanics and Design. Miller GJ, in Total Joint Replacement, W. Petty (Ed.). Philadelphia: W.B. Saunders Company (in press).

[368] Rehabilitation Implications of In Vivo Hip Pressure Measurements: Part 1

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Sponsor: VA Rehabilitation Research and Development Service (Project #A352-2RA)

Purpose—How cartilage distributes the time- and position-varying load across a synovial joint is of interest clinically as it relates to the longevity of endoprosthesis implantation following femoral head or neck trauma or necrosis. Migration of the implant through the acetabular cartilage is common: a 50% incidence of protrusion four years postoperatively has been reported. Pathologically, cartilage pressure distribution is central to the possible role of mechanical factors in the etiology of osteoarthritis, acting either directly (e.g., collagen fiber rupture), or through mechanical/biological coupling (e.g., the influence of the mechanical microenvironment on chondrocyte metabolism and expression). Scientifically, pressure distribution information is a crucial element in the basic understanding of how the mechanical and biological

characteristics of cartilage, bone, and synovial fluid synergize locally and globally to achieve high load capacity, low-friction, long-wearing skeletal bearings.

Prior to our research, only sparse *in vitro* data from rather gross experiments were available on the magnitude and distribution of contact stress in synovial joints. In general, these studies described the natural global joint as distributing the load vector into a more-or-less uniform or axisymmetrical distribution with maximum pressures not much higher than that calculated by dividing estimates of the load magnitude by estimates of the area of interarticular cartilage contact. This “average” pressure is about 2 to 3 megapascals (MPa).

Cartilage *per se* is a relatively soft, poroelastic matrix which is saturated with fluid. When small plugs

of cartilage are loaded to permit fluid drainage, the intrinsic or network modulus is measured at about one MPa. Mathematical models of simplified joints studying fluid circulation have in fact postulated free-draining or porous sliders, influenced apparently by the plug experiments.

Methodology—After considering different approaches to experimentally quantify local pressures and their distribution in the human hip joint, we chose to integrate multiple pressure transducers into the load-bearing surface of a pseudofemoral head, in part because hemiarthroplasty is a common surgical response to femoral head or neck damage. Thus, *in vivo* instrumented endoprosthesis data are relevant to a significant patient population and the surgeons who service them. These data are also pertinent to scientific understanding of normal and pathological synovial joint tribology and the etiology of osteoarthritis.

Results—The first prosthesis was implanted in 1984, and produced extensive data for over 5 years (see Part 2).

A second prosthesis was implanted in the fall of 1990. Significant design improvements have been incorporated based on experience with the first implant. The distribution of the 14 pressure transducers has been changed to include those locations on the femoral head which consistently reported data of interest as the subject performed a wide range of movements and loading patterns. The mounting of the single-silicon-crystal cantilever beams, the flexion of which measures cartilage pressure, was changed. The first design called for epoxy cementing, which exhibited cold flow and calibration deterioration on several of the transducers after several years. An all-mechanical clamping technique was devised and extensively tested which eliminates this problem. This new arrangement also facilitates the precalibration adjustment of the beams relative to the pressure diaphragms and the interconnecting push-pins.

Separate *in vitro* studies of temperature rise by “walking” human cadaver hip joints in the Hip Simulator had indicated significant temperature rise. Subsequent biochemical studies on chondrocyte response to these

temperatures caused the expression of “heat-shock” proteins. The Berlin group has recently reported similar temperature rise *in vivo* from their force-instrumented total hip replacement prosthesis. To better monitor temperature on and in the endoprosthesis, a dummy pressure transducer diaphragm was added and instrumented with a thermistor. This detector will also be used in a feedback control system to reduce the power inductively transmitted from the external coil to the antenna on the stem of the prosthesis.

The electronic package which converts the pressures, expressed as the strain-gauge signals, from the individual flexing beams to a pulse-amplitude-modulated signal for frequency modulation telemetry outside the human body, was extensively redesigned. Restudy resulted in part from changes and improvements in electronic components since the original unit was designed (large-scale integrated circuit “chips”) and in part to increase the number of channels from 16 to 32 to accommodate the temperature measurements, the power feedback control, and the future force vector and moment measurement.

Future Plans—A third prosthesis is underway. The major mechanical components are complete and fabrication will commence subsequent to implantation and completion of the early experiments with the second unit. During surgery, postsurgical management, and early rehabilitation, much data is acquired which requires the participation of all staff, with other tasks and assignments postponed.

Implications—Data from the second and third prostheses will confirm the consistency of data across subjects under similar experimental conditions.

Recent Publications Resulting from This Research

An Instrumented Endoprosthesis for Measuring Pressure on Acetabular Cartilage In Vivo. Mann RW, Burgess RG, in Proceedings of the Workshop on Implantable Telemetry in Orthopaedics, Berlin (in press).

[368a] Rehabilitation Implications of In Vivo Hip Pressure Measurements: Part 2

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Sponsor: VA Rehabilitation Research and Development Service (Project #A352-2RA); National Institute on Disability and Rehabilitation Research

Purpose—Surgical reconstruction or replacement of the human hip joint following trauma or arthritis is a very common occurrence, involving (in the United States alone) over four hundred thousand people each year. The surgical procedures include total replacement of both femoral and acetabular components of the natural joint with artificial prostheses, replacement of only the femoral component (usually following femoral neck fracture), and osteotomies where the natural components of the joint are retained but realigned. Whatever the intervention, the patients must be managed during an immediate postsurgical period of immobility. They then progress through a transitional process of rehabilitation which takes them, in stages, through more demanding movement patterns, until they regain full capability and can perform other activities of daily living. The patient management and physical therapy protocols applied throughout this process are essentially similar, whatever the particular hip surgery. Subjective generalizations derived from past experience with similar patients determine the optimum ordering, best postoperative time for initiation, appropriate duration, and content of each protocol of these management and rehabilitation practices. Thus, protocols which are vital to the rapid, safe, and full recovery of the patient rest solely on qualitative observations and *ex post facto* outcomes. *De novo* quantitative objective data are now available to evaluate these traditional processes and to consider alternatives.

Progress—Novel data from a pressure-instrumented femoral head replacement procedure have now provided objective, quantitative information on the mechanical environment of the human hip joint during surgery, postoperative management, throughout the process of rehabilitation, and in the activities of daily living. These data are challenging contemporary patterns of patient care, therapy, and rehabilitation, and provide objective data on which to classify the strenuous character of many normal and common movement patterns.

Methodology—A pressure-instrumented prosthesis with 14 small sensors integral with the spherical, metal, pseudofemoral head measures the focal pressure experienced by acetabular cartilage as it articulates against the femoral component. The first unit was implanted in June 1984. Data were acquired during surgery, postoperative recovery, immobilization, mobilization while in bed, early muscle exercise, all stages of ambulation (i.e., parallel bars, walker, crutches, and cane), and then during normal gait and other movement patterns such as rising from a chair, stair-climbing, jumping, and jogging, for a total period of over 5 years. During movement protocols, the pressure data are complemented with six degree-of-freedom kinematic data from the body segments of the lower extremity and the pelvis, and the foot-floor forces measured on dual forceplates. Very high local pressures measured during certain movements indicate significant muscle cocontraction, which has been confirmed from concurrent electromyographic data from the major muscle groups crossing the hip joint.

The pressures measured during the various stages of recovery and rehabilitation are of direct relevance to the evaluation of traditional rehabilitation procedures. Much of the data demonstrates inconsistencies with what has been presumed to be meritorious and commonly accepted rehabilitation practice, both in ordering and timing. To cite several examples, most of the present immobilization practices produce higher maximum pressures than pedaling a stationary bicycle, a common early mobilization procedure. Muscle contraction exercises performed in bed, well before attempts at ambulation, produce pressures of the same magnitude as those during the stance phase of level walking measured a year postoperative. Little correlation exists between the recorded maximum pressures and the current sequence in ambulation therapy (i.e., first parallel bars, then walkers, then crutches, then canes). The measured hip pressure is little affected by the force applied to the partial-load-bearing cane. The maximum pressures measured during walking indicate no further rise after 6 months, which correlated with the

clinical observation of achieving normal gait. The highest pressure measured was 18 MPa when rising from a normal (45 cm) chair. Astoundingly, this high pressure is higher than that produced when a hydraulic jack lifts a car.

Implications—This new quantitative pressure data can provide the basis for a more rational definition of appropriate protocols applied during recovery and rehabilitation following major hip surgery. The longitudinal data may explain why acetabular protrusion sometimes occurs following femoral head replacement. We believe the congruence of the metal ball to the natural acetabular cavity—both diameter and geometry—is critical, as demonstrated in our *in vitro* studies. The new data are also influencing surgical practice by indicating the directions of maximum pressure; accordingly, surgeons are using bone grafts to strengthen challenged regions of the pelvis.

Future Plans—A second pressure-instrumented prosthesis which incorporates a number of design improvements is ready for implantation. A future, more extensive series

of implants has been proposed which would augment the pressure data with direct measurement of the force vector across, and the moments about, the hip joint.

Recent Publications Resulting from This Research

- Contact Pressures from an Instrumented Endoprosthesis. Hodge WA et al., J Bone Joint Surg 71-A(9):1378-1386, 1989.
- Effects of Isokinetic and Isotonic Exercise on In Vivo Hip Contact Pressure. Elbaum LE et al., Transactions of the 35th Annual Meeting of the Orthopaedic Research Society, 225, 1989.
- The Effects of Running and Gaining Weight in Comparison with Normal Gait on Pressures Measured in the Human Hip Joint. Harris CL et al., in Proceedings of the 13th Annual Meeting of the American Society of Biomechanics, Burlington, VT, 174-175, 1989.
- In Vivo Hip Contact Pressures During Exercise and ADL. Krebs DE et al., Phys Ther 69:384, 1989.
- An Instrumented Endoprosthesis for Measuring Pressure on Acetabular Cartilage In Vivo. Mann RW, Burgess RG, in Proceedings of the Workshop on Implantable Telemetry in Orthopaedics, Berlin (in press).
- In Vivo Pressures on Acetabular Cartilage Following Endoprosthesis Surgery, During Recovery and Rehabilitation, and in the Activities of Daily Living. Mann RW, Hodge WA, in Proceedings of the Workshop on Implantable Telemetry in Orthopaedics, Berlin (in press).

[369] Optimized Surface Bonding and Stiffness of Femoral Endoprostheses

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Sponsor: VA Rehabilitation Research and Development Service (Project #A498-RA)

Purpose—Loosening of the femoral component is the most common complication of total hip replacement. The objective of this investigation is to determine the optimal surface characteristics and material properties for a femoral endoprosthesis to avoid loosening. The specific short-term objectives are to investigate the following design parameters using finite element modeling techniques: 1) the shape of the stem; 2) a presence of a collar for calcar contact; 3) the surface distribution of bone-prosthesis bonding for porous or ceramic coated stems; 4) the elastic modulus of the prosthesis; and, 5) the role of Coulomb friction at the bone-prosthesis interface.

Methodology—This investigation employs computer-based three-dimensional (3-D) structural models using the finite element method. Iterative solution procedures, based on mathematical optimization, are also being developed. New nonlinear contact surface algorithms,

which include Coulomb friction, are also employed in two-dimensional (2-D) models.

Progress—A 3-D finite element model of an intact femur was developed. This model was then modified to include a conventional straight-stem femoral component with a collar for calcar contact. A third 3-D model was developed by replacing the straight-stem component with a contemporary canal-filling femoral stem. Two large series of analyses were performed in which the area of bone-implant interface bonding was incrementally varied. Nonlinear gap elements were used at unbonded areas to simulate frictionless contact. Separate analyses were performed for cobalt-chromium, titanium, and carbon composite implants. The applied loads represented three phases of gait, stair ascent, and various isometric exercises.

Most recently, a 2-D model of an axisymmetric stem in diaphyseal bone was developed. This model included

nonlinear contact surfaces. Unlike the gap elements used in the 3-D models, these contact surfaces are capable of large displacements and include Coulomb friction. Analyses are currently being performed of axisymmetric models and plane stress models with side plate elements to evaluate various modeling techniques.

Results—The bone-prosthesis interface properties had a strong influence on the stresses in the supporting bone. Cementing the femoral component resulted in the most stress protection of the metaphyseal cortical and trabecular bone, followed by the fully-ingrown porous-coated implant, while the press-fit implant resulted in the least stress protection. In the more distal sections, the differences were small. The predicted stress protection in the metaphysis and proximal diaphysis agreed with published data.

The location of the maximum predicted interface normal stress in the bone was highly dependent on the region of interface surface bonding. It generally occurred at the distal boundary of the bonded region, due to the transfer of stress from the prosthesis to the bone. However, the peak principal stresses in the cortical bone proximally, were not highly dependent on the amount of surface bonding, and their magnitudes leveled off as the

region of bonding extended to the distal stem. The peak shear stress at the interface consistently occurred at the distal edge of the bonded area. As the surface area of bonding was limited to proximal regions of the stem, large compressive interface stresses were predicted, which could exceed the strength of the supporting bone.

Future Plans—Our current objective is to apply various objective functions and constraints to determine the best distribution of bonding from the existing analyses. We will then make incremental changes and perform additional analyses to determine the optimal solution. Several objective functions will be tested, including minimization of the stress differences between the intact femur and the femur with the endoprosthesis, subject to constraints on the shear stresses at the bone-implant interface. The 2-D models will be completed in order to investigate the relationships between Coulomb friction and subsidence and micromotion.

Recent Publications Resulting from This Research

Parametric Analysis of the Interface Mechanics and Material Properties of a Straight-Stem Femoral Component for Total Hip Arthroplasty. Cheal EJ et al., First World Congress of Biomechanics, 1990.

[370] Use of Proximal Femoral Allografts in Total Hip Revision

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Sponsor: VA Rehabilitation Research and Development Service (Project #A548-RA)

Purpose—Insufficient bone stock in the proximal femur is a frequently encountered problem in revision hip replacement, leading many surgeons to replace deficient host bone with a proximal femoral allograft. A major problem, however, is establishing union between host femur and allograft. A nonunion rate of 10% has been reported with cemented fixation. If the distal stem is press fit into the host bone, substantially different mechanics would likely occur at the allograft-host bone interface, differences which may enhance their union. The purpose of this study is to compare these alternative methods of distal stem fixation when used with a proximal femoral allograft in total hip replacement.

Progress—The first phase of this project (an *ex vivo* study comparing mechanics at the allograft-host bone

interface for cemented versus press fit distal fixation) has been completed.

Methodology—Ten large cadaveric canine femora were used to simulate preoperative and acutely postoperative conditions. Allografts were simulated with proximal femoral autografts, making the bone graft ideally sized. Femoral components were press fit into each medullary canal. Three stacked rosette strain gages and three eddy current transducers (ECTs) were adhesively bonded to the bone, measuring strains near the allograft-host bone interface and relative displacements of the allograft, respectively. Axial loads and transverse loads (torsion producing) were applied to the femoral (or implant) head.

Testing on each femur was performed in the following sequence: 1) control (intact femur); 2) press fit femoral

implant (no graft); 3) femoral implant cemented to proximal autograft and press fit distally; and, 4) femoral implant cemented proximally and distally. From the strain gage data, principal strains and strain energy densities (SED) were calculated.

Results—As a general trend, maximum compressive principal strains decreased as the testing sequence progressed for axial loading cases. A similar behavior was observed with SEDs. In each case, the cemented group consistently produced the lowest absolute strain. This effect was significant in all minimum principal strain comparisons at two of the three rosette locations. For torsional loads, the absolute strain in the cemented group was always smaller than the press fit group.

The distally cemented group had small relative displacements of the allografts. In contrast, each specimen in the press fit group had high relative displacements in

at least one ECT for at least one loading condition. The transverse ECT typically measured relative displacements greater than 1 mm for both axial and transverse loadings.

Future Plans/Implications—Cemented distal fixation provides a stable structure for allograft augmented total hip revisions, but it reduces the load transfer at the allograft-host bone interface, when compared with a distal press fit. This decreased load transfer may contribute to nonunions. The alternative of a distal press fit was unstable in at least one mode of loading in our experiments. The design of the distal stem used in this study probably contributed to this instability. If stability can be obtained with an alternative (press fit) stem design, load transfer advantages may exist at the host bone-allograft interface. Therefore, an alternative design for the distal stem was formulated. This design is currently being manufactured and will be used in future *in vivo* canine studies.

[371] Dynamic Implant for the Development of a Cementless Prosthesis

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Sponsor: National Science Foundation

Purpose—The aim of this project is to develop a biocompatible material with a range of mechanical properties similar to those of human compact bone. The ultimate goal is to use the new material as cementless prostheses, for example, joint implants.

Progress/Methodology—The general composition of this dynamic implant is a hydrophilic, crosslinked matrix reinforced with a three-dimensional (3-D) braided fiber structure. The stages of the development of the material system include the design and use of 3-D braid to achieve the desired degree of structural reinforcement; the selection of a candidate material for use as the matrix polymer base; formulation and optimization of the composition and the crosslinking scheme of the base polymer; development of a mechanical model to represent and predict the behavior of the composite structure under load; verification of the analytical prediction by testing the mechanical properties of the neat polymer and the polymer/braid-reinforced composite; and, evaluation of the interfacial pressure level to be utilized for *in-situ* implant fixation. Progress in each of these areas is discussed below.

Braid Design. Selection of braiding parameters is necessary to achieve the required degree of base-polymer reinforcement. The braid angle, the type and volume fraction of fibers, and the degree of fiber packing (beat-up) are optimized to provide a high level of compressive strength while retaining the high tensile strength inherent in braided structures.

Polymer Systems. Two different crosslinking agents are blended with the base monomer (acrylic acid) prior to its polymerization. The first crosslinking step occurs by a free radical mechanism during polymerization, while the second step involves using glycerol in a condensation reaction to be completed in the solid state by a postpolymerization heat-curing cycle which induces ester bond formation between the glycerol and the pendant acid groups in the matrix. Formation of the ester bonds is used as a final control on the resulting equilibrium pressure and is measured using TGA and FTIR techniques which are currently in progress.

Mechanical Testing and Evaluation. The crosslinking reaction of glycerol enhances polymer strength and modulus. However, unreacted glycerol acts as a plasticizer, lowering the same properties. To date, the mechanical

properties of the neat resin have remained significantly below those of compact bone. When a fiber network is introduced in the above system, it enhances both the strength and modulus of the matrix, and brings these properties within the target range for compact bone.

Evaluation of Interfacial Pressure. The interfacial pressure between the implant and surrounding bone is used to affix and hold the structure in place and accelerate bone response and densification. Thus, radial stresses are being measured as a function of time using cylindrical specimens incubated in Ringer's solution, while fitted in a metallic mold of the same size as the dry sample.

Development of a Finite Element Model. In the present analysis, a 3-D orthotropic braided structure is

taken into consideration. The procedure to determine the geometry and mechanical properties requires an initial postulation of a set of mechanical parameters. The braided geometry is then estimated by minimizing the total strain energy, or employment of the Tsai-Hill yield criteria. Currently, attempts are being made to estimate the overall stresses due to swelling of the hydrophilic matrix.

Recent Publications Resulting from This Research

A Dynamic Implant for the Development of a Hip Stem Prosthesis. Sharda AN, Kamel IL, presented at the Annual Conference of the IEEE Engineering in Medicine and Biology Society, Philadelphia, 1990.

[372] Correlation of In Vivo Synovial Joint Pressure Data with that from Posthumous Hemipelvis and Proximal Femur Including Pressure-Instrumented Endoprosthesis

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Sponsor: Whitaker Foundation, Health Sciences Fund

Purpose—Only one pressure-instrumented femoral head prosthesis has ever been implanted; that prosthesis has been retrieved posthumously together with the proximal femur and hemipelvis. Data was acquired from this prosthesis for a broad spectrum of activities and positions throughout the five years that it was implanted. This extensive array of *in vivo* data can now be compared with *in vitro* data that can be taken during comparable experiments in the laboratory. *In vitro* experiments afford control over experimental conditions which are not possible *in vivo*, and which will assist in further interpretation of *in vivo* data. Evaluation of the state of the acetabular cartilage following five years of contact with a well-matched femoral head replacement will also provide information never previously obtained and relevant to longevity of this orthopaedic procedure.

Methodology—Hardware required for high-pressure calibration of pressure sensors in the prosthesis has been built and tested. Software for acquisition of data from the prosthesis is functional on a personal computer; thus,

pressure calibration can proceed. Calibration of the effect of temperature on pressure sensor output has also begun. The techniques for obtaining acetabular geometry measurements are being tested prior to application on the excised acetabulum. Static tests in the Hip Simulator, a multi-axis, electrohydraulic testing facility will follow, followed by dynamic experiments with the Hip Simulator under computer control.

Implications—Correlation of *in vivo* and posthumous *in vitro* data will permit confident quantification of the forces experienced at the hip joint in life. This information and the knowledge gained from the acetabular measurements are expected to influence the design of femoral head replacements and surgical procedures, both of which involve endoprosthesis and total joint replacement.

Recent Publications Resulting from This Research

Optical Verification of a Technique for In Situ Ultrasonic Measurement of Articular Cartilage Thickness. Modest VE, Murphy MC, Mann RW, J Biomech 22(2):171-176, 1989.

[373] Synovial Joint Biomechanics and the Pathogenesis of Osteoarthritis

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Sponsor: Whitaker Foundation, Whitaker Professorship of Biomedical Engineering, Newman Laboratory Fund

Purpose—Osteoarthritis, or degenerative arthritis, disables more Americans than any other disease, producing much pain and loss of mobility while causing the greatest loss of worker productivity. This project is exploring how the human hip joint accommodates the forces and displacements of normal movement, and whether, and how, these mechanical factors contribute to the pathogenesis of osteoarthritis, either directly or by affecting the biology of cartilage.

Methodology—The *in vitro* phase of the investigation involved analysis and experiment on human hips from cadavers and the development of a detailed mathematical model of the cartilage and bone in this ball-and-socket synovial joint. Results include interarticular surface stress and strain, fluid exuded/imbibed, fluid pressures and the interarticular flow paths, solid matrix friction, entropy generation, and consequent temperature rise.

The *in vivo* phase includes five years of unique pressure data from the human hip (see "Rehabilitation Implications of *In Vivo* Hip Pressure Measurements," pp. 291-294). We now also have the unique opportunity to study *in vitro* the acetabulum and the pressure-instrumented endoprosthesis from which we acquired our

five years of *in vivo* data. We plan to both replicate *in vivo* experiments and perform tests not feasible in life.

Results—Computer simulations of the human hip synovial joint and correlating experimental data confirm the role of the interarticular seal in maintaining the high pressures, which for a healthy joint carrier, are typically more than 90% of the load. The degeneration of this seal is, we believe, tantamount to osteoarthritis. Accordingly, we are focusing on understanding the nature of this remarkable resistance to fluid flow. The cartilage-to-cartilage spacing in synovial joints in life is thought to be very small, but has never been measured.

A feasibility study of a technique to measure the interarticular gap using ultrasound has been carried out. Theoretical analyses for the experiments, the instrumentation, digital signal processing algorithms, and experimental techniques, have been developed and applied to the measuring technique with encouraging results. New ultrasonic instrumentation to be installed in a pseudo femoral-head prosthesis, in order to measure *in vitro* the global distribution of clearance between the prosthesis and the natural cartilage of the pelvis of a hip joint, has been designed.

C. Knee

[374] All-Plastic Total Knee Replacement

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Sponsor: VA Rehabilitation Research and Development Service (Project #A217-3RS)

Purpose—Greatly altered distribution of strain in bone surrounding metallic total joint replacement prostheses can lead to a net decrease in bone density, and an adverse biological response might be elicited by metal ions released from the device.

Our overall goal is to develop a total knee replacement made entirely from polymeric material (including fiber-reinforced polymeric composites). A specific objective is to test the hypothesis that a more compliant polymeric total knee replacement prosthesis

leads to more physiological remodeling of underlying bone.

Methodology—A radiographic evaluation of metallic total knee replacement prostheses in humans was undertaken to determine the prevalence of bone loss that might be due to the high stiffness of the device. This would serve as rationale for the development of an all-plastic total knee replacement prosthesis. The tribological performance of candidate polymeric materials is being assessed in a laboratory apparatus designed to evaluate various combinations of polymer-polymer articulation. Another apparatus is evaluating the morphology and size of wear particles that are produced as candidate biomaterials are abraded against bone (as might occur if the all-plastic knee prosthesis is employed as a cementless device). Prototype polymeric total knee replacement prostheses are being designed for implantation in dogs to evaluate tissue response.

Progress—In a retrospective radiographic review of 147 total knee arthroplasties, bone loss was found to occur in a distal anterior femur in 68% of the cases reviewed. The prevalence of bone loss was independent of mode of fixation (porous-coated versus cemented) and the implant design. Radiographically detectable bone loss occurred within the first postoperative year and did not progress further. Three-dimensional finite element analysis performed by other investigators has demonstrated that the replacement of the bearing surface of the femur with a stiff metallic implant reduces the stress in the distal anterior femur by at least one order of magnitude. We conclude that the bone loss resulted from stress shielding.

One series of wear studies employed a six-channel pin on flat wear-test machine-abraded candidate polymers against cortical bone slabs. The polymer specimens included: ultrahigh molecular weight polyethylene (UHMWPE), polymethylmethacrylate (PMMA), polyetherether ketone (PEEK) with smooth and textured surfaces, carbon-reinforced PEEK composite in parallel and perpendicular orientations, and polysulfone (PSF) in bulk and porous form. Titanium alloy served as the control. The operating conditions were: applied stress = 0.22 MPa, sliding speed = 24 mm/sec, temperature = ambient, lubricant = distilled water, duration = 32,000 cycles. Particles collected after testing were analyzed using

a laser light-scattering device and by scanning electron microscopy. The results of the wear debris analysis are: 1) porous PSF, size = $8.09\ \mu\text{m}$, SD = 3.37; 2) PSF, size = $6.96\ \mu\text{m}$, SD = 3.59; 3) textured PEEK, size = $22.67\ \mu\text{m}$, SD = 10.1; 4) smooth PEEK, size = $8.04\ \mu\text{m}$, SD = 4.81; and, 5) carbon-reinforced PEEK with perpendicular orientation, size = $10.44\ \mu\text{m}$, SD = 5.19. Statistically meaningful results were unobtainable for the titanium, UHMWPE, PMMA, and the carbon fiber-reinforced PEEK composite with parallel orientation. The size distribution for porous PSF and the bulk PSF were compared using an unpaired, two-tailed Student's *t*-test. No statistically significant difference was found to exist between the two materials. Results for the two different PEEK materials indicate that the particle size of the wear debris is much larger for the textured material than for the smooth. The two distributions were compared using an unpaired, two-tailed Student's *t*-test, with the result being significant at the $p < 0.0001$ level. Debris from the UHMWPE material exhibited a large aspect ratio (30:1). The particles were 10 to $15\ \mu\text{m}$ in diameter. There were insufficient numbers of particles to determine the average size statistically. The isolated titanium particles have a plate-like morphology with a thickness of 5 to $10\ \mu\text{m}$. The wear-tracks in the bone counterface materials were examined using a depth-indicating device. The results for the parallel and perpendicular composite materials showed a large difference. The perpendicular material produced a wear-track that was larger by an order of magnitude. The cause for this difference is believed to be fiber orientation. Delamination occurs in perpendicular fiber orientation (as seen on the wear pin face), resulting in debris generation and an abrasive wear mechanism. In contrast, the parallel orientation shows no delamination and the wear-track results are similar to those of bulk PEEK.

A second wear apparatus comprises four pneumatically-driven cylinders capable of applying physiological loads to specimens sliding on flat plates in a reciprocating motion. This machine determines the function and wear characteristics of polymer-polymer bearings.

Future Plans—A design project is underway to develop prototype composite femoral condylar prostheses for implantation into dogs.

[375] Articular Cartilage Replacement Prosthesis for the War-Injured and Aging

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Sponsor: VA Rehabilitation Research and Development Service (Project #A424-RA)

Purpose—Left untreated, focal defects in articular cartilage produced by excessive joint loading can grow to the extent that they lead to degeneration of the entire joint, and the need for total joint replacement. The objective of this investigation is to develop a prosthesis that can replace these focal defects in articular cartilage. In its initial form, this prosthesis would be a cylindrical implant inserted into holes drilled through the articular cartilage defects. The device would have a polymeric surface which would be capable of articulating against the opposing natural articular cartilage without causing accelerated degeneration of that or surrounding tissue.

Methodology—One task is to investigate the tribology of candidate materials to be employed for the articulating surface of the device. In a tribological apparatus, natural articular cartilage specimens are being rubbed against candidate polymeric substances. The coefficient of friction and the degradative changes of the articular cartilage are being determined.

Another task has been to develop a method to assess the "biocompatibility" of candidate polymeric materials to be employed for this application. Human peripheral blood monocytes, obtained from human volunteers, are being cultured on polymeric substrates. The production

of inflammatory agents including prostaglandin E₂, interleukin-1 and interleukin-6 are being evaluated using radioimmunoassays.

An animal model is being developed to evaluate the efficacy of the articular cartilage replacement prosthesis (ACRP). Cylindrical holes drilled in the patella of dogs are to serve as the test sites for evaluating the performance of candidate ACRP constructs.

Progress—The fabrication of ACRP constructs has been accomplished by bonding elastomers (e.g., silicone and polyurethane) to a porous thermoplastic (e.g., polysulfone) substrate, which is to serve as the attachment vehicle to bone. Mechanical testing is being performed to compare the mechanical properties of the ACRP constructs with certain properties of natural articular cartilage.

Cell culture assessment of the relative "biocompatibility" of candidate polymers has revealed elevated levels of IL-1, IL-6, and PGE₂ produced by monocytes cultured on ultrahigh molecular weight polyethylene. Other polymers are undergoing evaluation.

A surgical procedure for implanting ACRP constructs into the dog patella has been developed. Animal implantation is underway.

[376] Improved Anchorage of Knee Replacements Based on Confirmed Design Rules

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Sponsor: VA Rehabilitation Research and Development Service (Project #A546-RA)

Purpose—The goal of the proposal is to develop a tibial component of an artificial knee joint for fixation by osseointegration. It has long been known that the anchorage of the tibial component in human knee implants tends to fail whether a cemented or a porous-coated design is used. In fact, loosening of the tibial component is the most frequent single cause of failure in total knee replacement.

Progress—We have developed a tibial stem with a surface design intended for cementless fixation by osseointegration. To date the prototype of the total knee replacement has been manufactured using computer-aided design and machining based on the dimensions of dog knee X-rays. A cemented femoral stem with a hinge is attached to the uncemented, "press-fit" tibial component. A total of four titanium knee joint prostheses have been implanted in

short-time survival dogs. One prosthesis has recently been implanted in a long-term survival dog. At present, histomorphometry equipment and the pertaining software for analysis of the efficacy of osseointegration at the bone implant interfaces are being tested. The system was operational by the end of September, 1990.

Methodology—The design will be tested in 40 dogs to be sacrificed at specific time intervals (1, 2, 4, and 8 months) postoperatively. The implant performance will

be evaluated by mechanical testing of the strength of fixation of the bone-implant interface and by histomorphometric analysis.

Future Plans/Implications—The first 15 knees were implanted by the end of December 1990. It is anticipated that the remaining 25 knees will be implanted by July 1991. The mechanical and histomorphometric evaluations will be completed in December 1991. If successful, the design may form the basis for the development of human implants.

XII. Orthotics

For additional information on topics related to this category see the following Progress Reports: [7], [8], [9], [14], [85], [95], [104], [148], [149], [150], [151].

[377] Adjusted Versus Unadjusted Foot Orthoses in the Prevention of Foot Ulcers in Diabetics

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Sponsor: VA Rehabilitation Research and Development Service (Project #607-RA)

Purpose—Preulcerative and ulcerative foot lesions in diabetics invariably occur at weightbearing sites with maximum pressure. There is evidence to suggest that custom foot orthoses mitigate such pressures, presumably through their redistribution. We hypothesize that individually adjusted orthoses reduce the incidence of foot ulcerations. We also suggest that the effectiveness of orthoses and their best adjustment are possible with “in-shoe” capacitive sensor measurements which not only quantitate pressure, duration, and location, but can be performed on an outpatient basis.

The purpose of this study is to: 1) determine if in-shoe foot orthoses control distribution of plantar foot pressure in the stance phase of gait to such an extent that hyperkeratotic stance phase foot lesions are noticeably affected; 2) determine if orthosis adjustments significantly improve distribution of plantar foot pressure in the stance phase of gait, and if further orthosis adjustments are necessary with time; and, 3) determine, in diabetic

patients who have previously ulcerated their feet, if custom foot orthoses (adjusted versus unadjusted) decrease the incidence of reulceration.

Methodology—Two study groups will be used. Group One will consist of 40 subjects randomly assigned to the adjusted orthotic group. Group Two will consist of 40 subjects assigned to the unadjusted orthotic group. The adjustments will be made as needed, following determinations of foot pressure distribution during the dynamics of gait (pressure—N/cm², time—ms, and location in coordinates). The measurements will be obtained monthly using “in-shoe” capacitive sensor measurements.

Implications—We anticipate that adjusted orthoses will prove superior to unadjusted ones in preventing pedal ulcerations in the diabetic population. We also expect to find that in-shoe measurements of foot pressure distribution is the best method for guiding the appropriate adjustments.

[378] Clinical Evaluation of the Vannini-Rizzoli Stabilizing Limb Orthosis

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Sponsor: VA Rehabilitation Research and Development Service (Project #B597-EA)

Purpose—The purpose of this project is to evaluate the Vannini-Rizzoli Stabilizing Limb Orthosis (VRSLO) as a means to permit standing and ambulation, with a minimal expenditure of energy, in spinal cord injury (SCI) patients with paraplegia or paraparesis due to

lesions of the cord at, or caudal to, the mid-thoracic level.

Also included in the study is the establishment of the appropriate criteria for candidate selection, alteration of the treatment plans for those selected, selection of proper

exercises, establishment of the duration of the client's program, and incorporation of this information into the clinical application of the VRSLO or, as it is commonly referred to, "The Boot."

Methodology—The Boot works solely by arrangement and rearrangement of body mechanics. Use of the Boot causes plantar flexion of the foot and stabilization of the ankle; the patient is taught extension of the knees, hips, and back to achieve a stable stance. When proper weight-shifting techniques are combined with stance, the person may ambulate with a pendular motion of the unweighted limb and an assistive device (e.g., canes, walker, etc.) for support. SCI injuries ranging from C-6 to L-3 have been fitted, but ambulation status obviously differs from person to person.

There are several important variables which correlate with potential for success or failure. Patients with recent, low-level injuries and no major joint contractures or severe spasticity are good candidates. Persons must be highly motivated toward standing and walking, as well as willing to devote approximately 2 months to the program, 5 or more days per week.

Relative, but not absolute contraindications to participation include cardiovascular disease, history of long-bone fracture within one year of fitting, and placement of rods for spinal stabilization (which may limit back extension). Obesity, uncontrollable spasticity, chronic skin breakdown, and fixed joint contractures are definite contraindications.

The program consists of extensive exercises on a mat to facilitate weight-shifting movements, abdominal strengthening, and general stretching of the limbs and back. Daily sessions in the standing frame help develop tolerance for the upright position and allow further practice of weight-shifting techniques. Therapists assist with and supervise these activities.

Training with the orthotic devices begins after 4 to 6 weeks of the conditioning program. Patients are issued their Boots, and adjustments to the laces and soles are made to assure good fit and stability while standing. Both orthotists and therapists work with the patient in this phase. Candidates, in general, progress from using parallel bars for support to walkers, forearm crutches, or even canes.

Further refinement of skills may incorporate stair climbing, ramp walking, and car transfers, in addition to performing activities of daily living (ADL) while standing. Not all patients have, as yet, reached these goals; a major obstacle for some is adherence to the rigorous

program. For others, back or joint pain sometimes limits duration of use of the orthosis.

Progress/Preliminary Results—*James A. Haley Veterans' Hospital, Tampa, FL.* The Tampa VA Hospital has been approved to accept 30 patients for evaluating the Rizzoli orthosis. Thus far, 19 patients have been accepted in the research program. Ages range from 19 to 60 years old with length of injury from one year to 38 years. Levels of injury range from complete C-7 quadriplegia to L-1, L-2 paraplegia.

The Vannini-Rizzoli Boot has been very successful. Patients are ambulating with quad canes 60 to more than 1,000 feet (average distance 300 feet) for a success rate of 80%. Some patients are capable of negotiating stairs independently.

This new orthosis has increased independence, allowing patients who have been in wheelchairs for as much as 38 years to ambulate independently in their homes and moderate distances outside their homes. It has eliminated the need for some patients to make structural changes to their homes since they can ambulate independently. Several patients have stated that they have not had a urinary tract infection since using the Boots. Others have stated that they do not need to look for a wheelchair-accessible hotel when on the road. These are just several advantages the Boot has given our patients.

VA Medical Center, Bronx, NY. Dr. Vannini, developer of the Vannini-Rizzoli Boot, visited our center initially to assess interested candidates for the program. She was accompanied by a therapist and prosthetist-orthotist who were involved in her program. Twenty-four candidates, recruited through efforts of our staff and the Eastern Paralyzed Veterans Association, appeared. Although definitive criteria for admission into the program had not yet been finalized, 18 of these candidates were accepted. Of the first 18 patients, 6 completed the program and were given the Boots to use outside of the hospital. The others had to drop out for various reasons—the primary reason being their lack of endurance in mastering various stages of the protocol.

Subsequently, several more candidates entered the program; at the present time, we have 9 patients using the Boots.

We are continuing the program, but have had only a rare candidate. At the present time, we have two patients actively engaged in the training process.

VA Medical Center, Memphis, TN. As of fall 1990, 54 patients have been evaluated for the VRSLO and 25 have been selected, with an additional two patients in the

evaluation phase. Of the total selected, 21 are paraplegics with an injury level ranging from T-4 to L-3, complete and incomplete, and four are quadriplegics with injury levels of C-6 to C-7, complete and incomplete.

Of the 21 paraplegics selected, the functional levels are as follows: two require minor assistance for standing with the use of parallel bars or walkers, five are independent in ambulation in the parallel bars, five are independent in ambulation utilizing a walker, one is ambulatory with crutches, one is independently ambulating with bilateral quad canes, and one is independent in ambulation with a single quad cane and can also ambulate behind a wheelchair. Of the paraplegics selected, two can ambulate short distances with no assistive devices such as walkers or canes. There are also five paraplegics who can negotiate stairs, and two paraplegics who withdrew from the study; one for medical reasons and the other voluntarily.

For the quadriplegic group, the four patients selected have attained the following levels: two are independently standing with the use of a walker, one requires minimal assistance to stand in the parallel bars, and one has a permanent orthosis on order.

The preliminary results of the study have shown that the VRSLO is more widely accepted by the SCI clients than conventional bracing. The Boot is lighter in weight, more cosmetically acceptable, and easier to don and doff than conventional bracing systems. It is also apparent that the Boot is more functional, and due to the ability to attain static equilibrium with proper fitting, that the knee joint is free and mobile with no external locking mechanism.

Edward Hines, Jr. VA Hospital, Hines, IL. Our experience at Hines has been a mixture of results: some positive, others not entirely satisfactory. Of 20 pairs of Boots fitted, 9 persons appear to be daily users. At least one person has sustained hairline tibial plateau fractures (possibly a result of tibial torsion in the Boots), and does not ambulate at present. One patient relinquished his place in our program to attend to a severely ill spouse; another was employed in research which did not allow an extended leave to master the orthosis. Obtaining assistive devices with the length necessary to accommodate the additional height of a person in Boots has limited progress in several cases.

VA Medical Center, Long Beach, CA. Thirty patients aged 22-68 years are in this study. Spinal cord levels of injury vary from C-5 to L-1. Patient selection and other pertinent data are given. Our results indicate a success rate of more than 90%. Acceptance of the Boot has been

extremely good. The average distance ambulated was 100+ feet.

VA Medical Center, Brockton/West Roxbury, MA. Twenty-five patients were initially evaluated: 17 were entered into, and 7 completed the study. After discharge from the intensive exercise program, patients were evaluated at least monthly for the first 3 months, and then at least every 3 months. Of the seven who completed the study, four are ambulating at a community level and one at the household level using canes. Five were unsuccessful in using the VRSLO to ambulate because contractures could not be eliminated, skin breakdown occurred on the feet, or a tibial fracture occurred after admission to the study but before the Boot arrived. Three of these "failures" were temporary. These patients will be reentered into the study after the musculoskeletal or cutaneous lesions heal.

Future Plans—*VA Medical Center, Bronx, NY.* Our therapists and orthotists are well trained and can handle new candidates expertly. We anticipate relatively few new participants. However, the therapists will continue to do periodic follow-up evaluation on all patients who have been issued the Boots, and we shall cooperate with the other five medical centers in achieving the goals and evaluating the effectiveness of this pilot program.

VA Medical Center, Brockton/West Roxbury, MA. Admission criteria will be liberalized to include older patients and those with lesions between T-2 and T-6 to learn if they also can benefit from the Boot. Evaluations of oxygen and energy consumption will be made to compare metabolic efficiency of the Boot with long leg braces.

Implications—Data combined from the six original sites suggest that the VRSLO is a viable means of achieving gait in the spinal cord injured. Several sites are interested in quantifying energy requirements of the VRSLO when compared to long leg braces and/or wheelchair propulsion. The Boot is not a means of rapid propulsion, but bears certain aesthetic and functional advantages over previous orthoses of similar intent. Therefore, it may be more accepted (and utilized) by the SCI population.

Additionally, patients note subjective benefits of standing, such as reduced spasticity, better urinary and bowel elimination, and feelings of greater well-being.

This study has been recently expanded to include three more sites and should continue to provide information over the next few years regarding not only the orthosis itself, but many related SCI topics as well.

[379] Orthotic Stabilization of Thoracolumbar Injuries

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Sponsor: VA Rehabilitation Research and Development Service (Project #A509-RA)

Purpose—Spinal orthoses have traditionally played an important role in the early mobilization of patients with thoracolumbar injuries. However, the treatment protocol for orthotic management of spinal fractures remains subjective due to a lack of objective data defining the three-dimensional (3-D) instability of spinal fractures and the extent to which different spinal orthoses can improve the biomechanical stability of the injured spine. The objective of this study is to evaluate the effectiveness of spinal orthoses in controlling the progression of deformities at the injured segments under the action of different loads and for different severity levels of injury.

Progress—To date, we have demonstrated the methodology for a 3-point hyperextension orthosis. A finite element model (FEM) of the ligamentous spine with ribcage was used. The model consisted of 17 beam elements; each beam element representing the overall contribution of all anatomical components of a spinal segment. An injury of increasing severity was simulated by progressively reducing the stiffness of T11-T12-L1 segments. Interaction of a 3-point hyperextension brace with the spine was simulated using experimentally measured stiffness properties of the brace. The model was used to predict displacements at the injured segment and loads exerted by the orthosis on the trunk.

We are currently extending the above model to incorporate the detailed anatomical structures of the thoracolumbar region (T11-L2). This will allow us to simulate the damage to individual anatomical components associated with each type of injury, and thus, will facilitate clinical interpretation of model results. This model will be developed using the commercially available package, ANSYS. The cortical shell and the cancellous core of the vertebral body, and the posterior bony elements will be modeled as 3-D isoparametric 8-nodal brick elements. The annulus fibrosis will be modeled as a composite material consisting of fiber bands (lamellae)

embedded in the ground substance (3-D, isotropic 8-nodal elements) around the nucleus. Nucleus material will be modeled as a 3-D incompressible fluid element. The ligaments will be modeled as bilinear cable elements similar to annular fibers. Material properties for this modeling work will be derived from data in the literature.

We have also performed preliminary experimental studies to measure loads exerted by two types of hyperextension orthosis (Jewett and CASH) for different tasks using normal subjects. The loads were measured using thin arrays of Force Sensing Resistors sandwiched between the orthosis pads and trunk. The different postures were quantified using the WATSMART motion measurement system. Electromyographic signals were also recorded from the erector spinae and rectus abdominus muscle groups using bilateral surface electrodes while subjects performed different tasks. Data from a total of three subjects have been acquired and are currently being analyzed.

Future Plans—This project will investigate the biomechanical stability of spinal fractures stabilized with different spinal orthoses and surgical constructs, used alone or in combination. The response of orthotically supported injured spine to loads in three planes, and evaluation of other orthotic designs such as the total contact thoracolumbosacral orthosis (TLSO) will be investigated in the future. Further, experimental studies will be performed to measure changes in orthotic loads as subjects perform various tasks. The long-term goal of this study is to develop objective treatment guidelines to adequately protect patients with spinal trauma during the healing process of spinal injuries while preventing unnecessary surgery or bracing.

Recent Publications Resulting from This Research

Orthotic Stabilization of Thoracolumbar Injuries-A Biomechanical Analysis of the Jewett Hyperextension Orthosis. Patwardhan AG et al., Spine 15(7):654-661, 1990.

[380a] Concerted Action Mobility Restoration for Paralyzed Persons (MORE Project)

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Purpose—The Concerted Action MORE (MObility REstoration for paralyzed persons) has been launched by the COMAC BME (Committee for Management of Concerted Actions in BioMedical Engineering) in the framework of the fourth Medical and Health Research Programme of the Commission of the European Communities. This 4-year program started in 1988 and involves more than 50 Institutes located throughout the countries of the European communities. The Concerted Action is directed toward those who are paralyzed as a result of spinal injuries (i.e., paraplegics, quadriplegics), cerebral palsy, or neuromuscular diseases—people who represent a high percentage of the physically disabled. However, many other disabled persons could also benefit from the results of this action.

The objectives of MORE can be summarized as follows:

- Stimulate research of new technologies having meaningful and beneficial application for disabled users, particularly in the areas of: 1) new electrode materials, implantable multichannel stimulators, control strategies and implantation techniques for walking restoration in paraplegics; and, 2) new materials, ergonomics and design, seating and support systems, and control systems for technical aids for independent mobility.
- Multi-center trials of existing devices and new technologies and the exchange of evaluation results among the Centers involved in order to improve their value and reliability.
- Coordination of methodologies and protocols for technical, functional, and clinical evaluation of mobility aids. Technical evaluation is concerned with the technical quality and performance (e.g., materials, durability, safety, reliability, etc.) of equipment; functional evaluation is concerned with the effectiveness of equipment in meeting the actual needs of its disabled user; clinical evaluation is concerned with the effects on the user's health and compatibility with the body as it applies to some devices implanted or directly interfaced with the body (e.g., FES equipment).
- Gathering of research and evaluation results and dissemination to industries and/or rehabilitation

professionals. For such purposes, a close relationship has been established with: 1) the ongoing Handynet project—a section of the second program of Action in Favor of Disabled People (HELIOS) run by the Commission of the European Communities through the DGV, aimed at setting up a computerized information network concerned with the technical and social resources for rehabilitation and social integration; and, 2) the CALIES program (Computer-Aided Locomotion by Implanted Electrical Stimulation) launched in the framework of the EUREKA program.

Progress—In the field of *Walking Restoration* (WREP), particular consideration was given to the following aspects:

- Investigation into the basic mechanisms governing the control of normal gait (e.g., kinematics, dynamics, etc.), and identification of the optimal control signals used for stimulating a minimum set of muscles in paraplegic patients to restore walking in an acceptable manner. This study should lead to a general simulation approach for the best choice of the control laws in individual patients as a function of lesion, anthropometric characteristics, and eventual use of mechanical devices.
- Study of biocompatible materials, miniaturized hardware, and technical solutions for implantable systems, taking into account the problems raised by the wiring, connections, and implantable electrode interfaces.
- Study of the best electrical signals able to modulate muscle force and fiber recruitment in such a way as to minimize muscle fatigue.
- Clinical trials and development of suitable protocols for training and adapting devices to the individual patient.

In the field of *Mobility Restoration*, the following activities took place: participation in international meetings concerning the technical aspects of mobility and transport for paralyzed persons; the study and critical comparison of techniques and methodology for technical and functional evaluation of wheelchairs; and, investigation into new materials and technologies for wheelchair construction for achieving the best ergonomic performance.

Methodology/Results—In designing Concerted Action, we decided to concentrate specifically on the following topics on the basis of the present state of the market, the highest priority needs of a large number of paralyzed persons, and ongoing activities currently in progress in Europe: 1) Walking Restoration in Paraplegics (WREP), which includes mechanical devices, functional electrical stimulation (with implanted or surface electrodes), hybrid systems (combining mechanical devices and FES); and, 2) Technical Aids for Independent Mobility

(TAIM), which includes wheelchairs (manual and electric), cars (adaptation, modification of controls, special cars), and transfer aids (hoists for personal transfer, stair-climbers, etc.).

Implications—Technical aids for mobility restoration assume great importance in achieving independence for a better quality of life, social integration, access to job opportunities, school integration, and social relationships.

[380b] Muscle Recruitment Optimization in Walking Restoration by FES

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Purpose—The aim of this study is to develop proper procedures for choosing the best stimulation pattern for functional electrical stimulation (FES) in paraplegic patients with the goal of restoring their ability to walk.

Progress/Methodology—We have developed, and implemented on a computer, a simulated model of a person walking. The skeletal schematic had seven rigid links (three for each leg, one for head, arms, and trunk), and six joints (two hips, two knees, and two ankles). This model solves the direct dynamic problem of starting from initial conditions (position and velocity), when the time course of the segment positions is computed on the basis of mechanical torques applied to the joints.

To provide the necessary adaptability to an individual patient, the body segments' anthropometric parameters (mass, length, inertial moment, and gravity center position) are estimated automatically, starting with the subject's height and weight. Under the hypothesis of symmetry, periodicity of gait has been considered the interval between right and left heelstrike. The model is bidimensional, considering only movement in the sagittal plane.

The model is being tested with the time course of joint torques measured from healthy subjects, compared with measured kinematics of simulated ones. Starting from noncorrected kinematics, a trial and error procedure is used to correct the simulated kinematics modifying the input torques to obtain an optimal torque pattern.

Future Plans—A hybrid FES research program is being planned (in collaboration with clinical and rehabilitative groups), for the restoration of walking in incomplete spinal cord injured patients.

The model will be used as follows: 1) patient movement will be evaluated and the time course of the torque exerted at the joints during walking will be computed to measure kinematics and ground reaction forces; 2) computed torques will then be introduced as input for the simulation model, and making use of a trial and error procedure in combination with optimization criteria, the best muscle activation pattern will be derived; and, 3) this optimal pattern will then be applied to the patient, with the resulting kinematics evaluated with a quantitative analysis of the gait.

We also want to consider the "standing-up" movement and standing equilibrium with an adequate model, and study the relationship between stimulus and torque generated at the joint by induced muscular contraction.

Recent Publications Resulting from This Research

- Strategies in Muscle Recruitment for FES in Walking Restoration. Pedotti A, Ferrarin M, in Proceedings of the 11th Annual Conference of the IEEE Engineering in Medicine and Biology Society, Seattle, WA, 1989.
- A Modelling Approach to Stimulation Pattern Optimization. Ferrarin M, in Proceedings of the COMAC-BME Workshop "Restoration of Locomotion," Thessaloniki, Greece (in press).

[381] FES-Aided Paraplegic Gait Using a Controlled-Brake Orthosis

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Sponsor: *National Center for Research Resources, National Institutes of Health*

Purpose—Restoration of gait to paraplegics using functional electrical stimulation (FES) is a challenging problem. A crucial difficulty is controlling the FES system for stability and smooth gait. One option for improving control is to develop implanted systems with large numbers of stimulation channels and complex control algorithms. However, simple surface stimulation programs should continue to be explored because they involve no surgery. One means of improving walking function using surface stimulation is to add a mechanical orthosis in combination with FES.

Based on the preliminary work of our group, we are proposing to address the problem of designing a functional FES-aided gait system using surface stimulation by investigating a new device which may improve the quality of gait. The device incorporates a knee orthosis containing a controllable friction brake at the joint. The purpose of the brake is to shift the burden of control in a gait trajectory from controlling the stimulated muscles and spastic reflexes to controlling the brake, a well-behaved mechanical element. The controllable brake also provides a means of locking the knee joint during periods of quiet standing, which may reduce overall muscle fatigue. Further, the brake can provide a rigid brace mode which may be safer in the event of a stimulation failure.

To evaluate brake designs and performance, we will quantitatively test and compare the ability of SCI paraplegics to achieve FES-aided gait both with and without the brace. The assessment will include kine-

matic, dynamic, and metabolic variables.

Progress—Pilot studies based on stimulation of able-bodied subjects to control the knee joint demonstrated the utility of the controlled-brake approach. By combining fine control of the brake with gross control of muscle stimulation, performance on position tracking tasks was greatly improved over both open- and closed-loop control schemes which used stimulation alone. We have completed a computer-controlled, 8-channel stimulator and have begun clinical experiments at the West Roxbury VA Medical Center using ambulating paraplegics. To date we have implemented the standard 4-channel flexor withdrawal FES-aided paraplegic gait in a single subject who is T10 motor-complete.

Future Plans—Preliminary designs for a wearable version of a controlled-brake orthosis have been completed. After further development, we will build a brace and test our hybrid gait assist concept in experiments using paraplegic subjects.

Recent Publications Resulting from This Research

Open-Loop Position Control of the Knee Joint Using Electrical Stimulation of the Quadriceps and Hamstrings. Hausdorff J, Durfee W, Med Biol Eng Comp (in press).

Regulating Knee Joint Position by Combining Electrical Stimulation with a Controllable Friction Brake. Durfee W, Hausdorff J, Ann Biomed Eng (in press).

[382] Electrical Stimulation Strategy to Inhibit Spasticity During Gait

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Sponsor: *Easter Seal Research Institute of Ontario*

Purpose—Spasticity can be defined in terms of its characteristics, the most salient of which is an exaggerated stretch reflex. Previous work has shown that it is possible to inhibit the stretch reflex of triceps surae by electrically stimulating the antagonist tibialis anterior muscle. With recent evidence suggesting the influence of

the monosynaptic stretch reflex during gait, the aim of this project is to modify spastic gait by inhibiting the stretch reflex.

The project can be divided into two parts, each with its own specific goal. These goals are: 1) to determine the relationship between latency of stimulation, number of

pulses in one stimulus burst, pulse frequency, and amount of inhibition; and, 2) assuming that the stretch reflex of the triceps surae influences gait, to develop a stimulation strategy during gait which would modulate triceps surae tone.

Methodology—The study will involve subjects with mild spastic cerebral palsy. For the first part of the study, subjects will be seated in an Ankle Actuating Device, a computer-controlled system which can impose rotary movements about the ankle joint, causing a passive stretch of triceps surae. The tibialis anterior will be stimulated to inhibit the stretch reflex of triceps surae. Exploratory experiments will be performed to determine the relationship between the number of pulses, the stimulus

frequency, the latency, and the amount of observed inhibition. These results will allow us to determine electrical stimulus parameters that are efficacious in inhibiting the stretch reflex for use in the second part of the project. During gait, stimulation will be timed relative to depression of a footswitch placed on the bottom of a subject's foot. Exploratory experiments will be performed to determine the optimal latency relative to the footswitch depression for each subject. Using the VICON and EMG systems in the Gait Laboratory, an assessment of each subject's gait with and without stimulation will be made.

Progress—Equipment and software for both parts of the project has been completed, and the first part of the project has begun.

[383] Criticality of Fit of Ankle-Foot Orthoses

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Sponsor: Natural Sciences and Engineering Research Council of Canada

Purpose—The purpose of this project is to determine the critical parameters required for effective bracing of the lower limb with ankle-foot orthoses (AFOs). Research on the criticality of fit of AFOs will be conducted to investigate the feasibility of a non-intimately fitting AFOs. AFOs being prescribed today are custom-made for each child, with the leg and foot fitting intimately into the brace. It has been proposed that this intimate fit is required for the proper positioning of the foot to achieve optimal ambulation, and to prevent pressure sores in cases where the skin is insensitive. The fact that AFOs fit intimately creates several undesirable problems: a high production cost, a lengthy production time, and a short usable period.

The remaining sections of the AFO are presumed to play a much less important role. The points critical to the fit will be determined in this research. This project will limit itself to investigating AFOs used to treat valgus foot deformity associated with spina bifida.

Methodology—A three-stage approach is planned: 1) a mathematical model for the valgus foot deformity will be defined. X-rays of valgus feet will be examined and current models of feet will be researched to aid in this task;

2) the acceptable corrected foot position and allowable tolerances will be determined. Some subjective input from orthotists and therapists will be required, together with X-rays of foot position in currently used AFOs; and, 3) points where pressure must be applied to bring the foot into a corrected position will be determined. Static analysis will be used in conjunction with the previously defined model and corrected position.

The effectiveness of this bracing approach will be evaluated. An adjustable jig which will allow different children to be tested will be built for this purpose. With the required corrective forces determined and evaluated, follow-up will include building functional AFOs based on the derived information. The AFOs will be evaluated on the children with respect to comfort and function.

Implications—Positive results will encourage further design work into a non-intimately fitting AFO. The outcome could be a less expensive AFO constructed in a shorter period of time and with a longer usable period than presently available AFOs. The procedures used in this study could be extended to other foot deformities with the goal of obtaining corrective models and standardized AFOs for the most common foot deformity.

[384] Quick-Attaching Brace for Improved Paraplegic Mobility

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Sponsor: VA Rehabilitation Research and Development Service (Project #B486-DA)

Purpose—The goal of this project is to develop a lightweight, full-leg brace with an electrically locking knee joint. The major design requirements for this brace include the ability to: 1) hold 1300 in-lbs of torque around a medial-lateral axis with a brake actuator force of less than 5 lbs; 2) be locked or unlocked in less than 100 ms in any angular position; and, 3) be easily donned and doffed in a few minutes by a paraplegic while sitting in a wheelchair. This brace is intended to be used in combination with electrical stimulation of the leg muscles to allow paraplegics to stand and walk in areas inaccessible by a wheelchair.

Progress/Results—The major effort during the last year was made in the development and testing of the knee-joint. A band brake design was used for its simplicity and high mechanical advantage. It consists of a 1.35-inch radius drum covered with neoprene rubber, and a stainless steel band that is tightly wrapped around the drum when locked. The locking force of approximately 3 lbs is supplied by a spring attached to a lever. The brake is normally locked, and is unlocked by pulling on a string wound around a small motor shaft. To reduce weight at the knee joint, the actuator motor is located at the hip. Testing of the latest design has shown that the desired locking torque of 1300 in-lbs is achieved with a spring force of 2.5 lbs. The total lever arm movement required for actuation is approximately 1 inch.

This actuation is achieved with a dc motor that weighs 240 gm, and draws approximately 1 A of current at 12 V during actuation. The motor is able to unlock the

brake in 40 ms. The mechanical design and development of the knee joint are reported in greater detail in a 1990 master's thesis at the University of Utah.

Future Plans/Implications—During the remaining 6 months of the current grant, we expect to integrate the Rancho Los Amigos 8-channel stimulator, the actuator electronics, and the leg brace into a working unit, and perform preliminary durability bench testing of the total system. Modifications to the brace and electronics will be made as needed for a configuration that can be tested on human subjects.

The availability of a leg brace that is easily donned and doffed, is lightweight, and is locked or unlocked by electrical actuation would provide a basis of extending ambulatory function for many paraplegics who are now limited to wheelchair mobility. Such a brace may also see wider use. Prosthetists see the need for such a device in older post-polio patients. In these cases, electrical stimulation of paralyzed muscles may not be needed. However, a brace of the weakened leg and knee that locks and unlocks during the gait cycle may significantly improve the ambulation of this population.

Recent Publications Resulting from This Research

Design of a Locking Knee Joint for Use with Hybrid FES Systems. Long J, Schoenberg AA, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 375-376, 1990.

A Locking Knee Joint Design for Use with a Hybrid Functional Electrical Stimulation System. Long J, Masters thesis, University of Utah, 1990.

[385] Comparative Study of 49 Walkers

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Sponsor: American Association of Retired Persons

Purpose—Forty-nine walkers provided by 20 manufacturers were tested by 19 walker users.

Methodology—All subjects are using or had used a walker in the past year. Seven of the subjects were 55 to 70 years

old, and 12 were over the age of 70. Conditions leading to walker use included arthritis, hip surgery, fractures, weakness, balance problems, amputation, and paralysis.

Subjects were asked to open and fold, and to lift each walker. They used the walker for assistance in sitting

down and standing up. Each task was timed and subjects estimated their effort level for performing the task. Additionally, a physiograph was used to measure heart rate to determine level of exertion while completing the tasks.

Each walker was used to traverse four different surfaces. Subjects walked 50 feet each on a smooth indoor surface, a thickly carpeted floor, and an outdoor lawn. Subjects also walked 40 feet up and down a 12-degree ramp. Subjects tested walkers while carrying a weighted load and held the walkers in a locked position.

Walkers were categorized by number of wheels. The traditional rigid and folding walkers have no wheels (the "no-wheel" group). "Two-wheeled" walkers are structurally like the no-wheel walkers, but have a wheel on each of the front legs. The newest walker design has a wheel on each leg (the "4-wheel" group). The 4-wheel walkers vary the most in design, not only from the other two groups, but also within the 4-wheel group.

Results—The presence of wheels is the strongest predictor of user performance. On all tested surfaces, 4-wheel walkers outperformed 2-wheel walkers, which in turn outperformed no-wheel walkers. The reverse order was observed in opening and folding times, with the more complex 4-wheel walkers requiring the most effort. As an aid to sitting and standing, subjects gauged the

no-wheel and 2-wheel walkers more stable than the 4-wheel walkers.

Among walkers with wheels, there was a strong interaction between wheel size and type and walking surface. Small wheels tended to rattle and jam on uneven surfaces. Large wheels were harder to maneuver in tight spaces, but performed better than small wheels outdoors. Wheels with pivot mounts were easier to turn on all surfaces than rigidly mounted wheels, but were perceived by users as less controllable on uneven surfaces.

Walker height affected both user support and stability. A too-tall walker did not provide proper support; too-short walkers made the user uncomfortably stooped. Walker stability was a function of walker design, adjusted height, and supported weight.

For no-wheel walkers, the greater the weight of the device, the poorer the subject's walking performance.

Future Plans—Grip location and orientation on most of the tested walkers violates the standard ergonomic design guidelines for handles. Most of the best-performing walkers exhibited more than average rake on their front legs. Walkers with the base of the front legs or front wheels extended well in front of the hand grip position were perceived as more stable and easier to turn. Further research on these two design aspects is warranted.

[386a] Free Knee Brace System

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Sponsor: *Canadian Paraplegic Association*

Purpose—Individuals who have unstable knees must often resort to long leg braces for support. Walking with two long leg braces, without the ability to bend the knee, is clumsy and tiring. Our purpose, therefore, is to develop a knee brace which can lock and unlock automatically to allow the user's knee to flex as she/he walks.

Progress—The system we are building allows knee flexion when the leg is unloaded and being swung ahead, and locks the knee when the limb is loaded. The brace,

which consists of long leg braces for each leg, and a clutch at each knee, has been designed as an electro-mechanical device. Switches under the foot sense what part of the foot is in contact with the floor, a circuit "decodes" the signal, and locks or unlocks the knees as required. A "wrap spring clutch" has been chosen as the most appropriate clutching mechanism, and suitable electronics have been designed. A prototype brace has been built for use in evaluation of the system by our clinical collaborators.

[386b] Comparison of Velocity and Position Control Strategies for the Case Western Reserve University (CWRU) Upper Extremity FNS Orthosis

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Sponsor: Canadian Paraplegic Association; Natural Sciences and Engineering Research Council

Purpose—Our goals were to: 1) implement a velocity control strategy on the Case Western Reserve University (CWRU) Micromini FNS orthosis; 2) compare the effectiveness of velocity control with position control in the performance of a functional task and a step-tracking task; and, 3) determine the effects of varying the gain and dead-space parameters for a velocity control strategy.

Methodology—The Micromini FNS orthosis was designed to provide a C4-C7 quadriplegic person with some limited hand function (i.e., a palmar grasp toprehend large or cylindrical objects, and a lateral grasp to grasp small flat objects).

The CWRU strategy is position control, with hand position directly proportional to shoulder position. Each combination of hand position and force is achieved by modulating the pulse widths of electrical signals stimulating muscles in the hand and forearm.

An alternate strategy (velocity control) was developed wherein the shoulder position determines the rate and direction of change of the output function. In the center of the range of motion is a dead-space, within which a change in shoulder position does not affect the output function. Outside the dead-space, increasing protraction results in an increasing rate of hand closing while retraction causes hand opening.

A computer-based system consisting of software, A/D and D/A converters, and interface hardware was developed to evaluate position and velocity control strategies. Programs were also written to control low-level A/D and D/A routines and to calibrate the joystick.

For the functional assessment, a book (10.5 × 3 × 18 cm weighing 300 g) was moved from a midline resting

position on a table 79 cm high, to a book-holder on a separate shelf.

For the computer simulation tests, a non-random, one-dimensional step-tracking task was used. Three targets appeared on the screen. When a target was highlighted, the participant moved his shoulder so that the cursor would enter the target. To successfully acquire a target, the participant had to keep the cursor within the target for 0.25 s. Fitts' constant (a normalized measure of time) was used to measure performance and was calculated from Fitts' law, that is, time to target = Fitts' constant × log 2 (2 × target distance)/width.

Results—Position and velocity control were compared for reaching distances of 46 and 82 cm. At both distances, the mean time with velocity control was less than the mean time with position control. For 46 cm distance, the mean difference was 2.14 s (n=4, p<0.038), while at 82 cm the difference was 24.3 s (n=4, p<0.16).

An additional assessment was performed to determine if the addition of a dead-space to a velocity control strategy improved performance on a reaching task.

Implications—Protraction and retraction of the shoulder can be used by C4 and C5 quadriplegics to control velocity or position of a hand or cursor on a computer screen. Performance of velocity control is superior to that of position control. This is probably because in velocity control, any hand position can be maintained when the shoulder is relaxed. In position control, relaxing the shoulder causes the hand to return to its initial position.

[387a] Further Development of a Protective Helmet for Disabled Persons

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Sponsor: National Health Research and Development Programme, Department of Health and Welfare, Canada; Cooper Canada

Purpose—The purpose of this project is to develop protective headwear which provides effective head and facial protection for children who frequently fall. The specific goals are to: 1) develop a second generation helmet which provides appropriate anatomical protection, is custom-fitted, comfortable to wear, looks attractive, and is reasonably priced; 2) evaluate the biomechanical performance of the helmet in the laboratory; and, 3) assess the subjective acceptance and performance of the helmet through clinical trials.

Progress/Methodology—Creation of the “second generation” prototype has focused on the enhancement of its impact properties and structural integrity. Improvements in liner fit, ventilation, and hygiene are also intended without compromising the helmet’s general cosmesis.

Initially, a preproduction helmet was designed for children with nominal head circumferences in the 490-540 mm range (approximately 5-12 years of age). The prototype consists of a 3-piece, thermoformed Kydex shell—an anterior section, posterior section, and a chin cup—with a full-contact polyethylene foam liner of uni-

form thickness. The assembled helmet is shaped to provide both cranial and facial protection in the event of a fall. Heat dissipation is promoted at the top of the helmet through convection channels in the liner.

To ensure a good anatomical fit on the head, the three shell/liner parts are adjusted, located, and secured in place by an orthotist during the fitting. Further customization of the helmet is possible through the addition of liner inserts and trimming the helmet.

Both biomechanical and clinical testing of the prototype helmets were conducted to verify the concept. While the biomechanical tests demonstrated performance consistent with effective cranial protection, feedback from the clinical trials indicated modifications which should be incorporated into the production version of the helmet to enhance its serviceability.

Production tooling for modified, rotomolded shells and die-cut liners are being produced for both the small and large size helmets. It is expected that these sizes will meet the needs of most children between the ages of 5 and 19.

Biomechanical tests and clinical trials using the production helmets have begun.

[387b] Evaluation of a Powered Orthotic Device for the Enhancement of Upper-Limb Movement

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Sponsor: National Health Research and Development Programme, Department of Health and Welfare, Canada

Purpose—The objectives of this project are to: 1) determine the benefits of a powered orthotic hand and elbow developed at HMRC for people with severe upper limb weakness due to amyotrophic lateral sclerosis (ALS); and, 2) identify future enhancements to the powered orthosis in order to further enhance the independence of individuals with ALS.

Progress/Methodology—The powered orthosis consists of two spring-loaded ball-and-socket elbow joints, two steel rods, a rigid rod corresponding to the ulna and a telescoping rod corresponding to the radius, and a hand brace with a single axis joint. The hand joint is opened and closed in a palmar grasp by a linear actuator, and the elbow is activated by the power winch unit. When the

elbow joint is flexed, the forearm is partially supinated due to the diagonally-applied force on the ulnar rod and the extension of the telescoping radial rod.

Powered Linear Actuator. Housed in a slender aluminum tube, the linear actuator is powered by a commercially available motor/gear box combination. A one-quarter-inch ACME screw is attached directly to the gear-box output shaft and is supported by an anti-thrust ball bearing to support axial loading in both directions. The screw engages with a nut located at the end of the orthosis to achieve the desired moment at the hand. At the end of the actuator, a swivel bracket is provided to mount the assembly onto the orthotic frame. The system operates on six volts, has a stroke of 1.5 inches (which is greater than other actuators) and is able to deliver a force of 14 lb. Plans are underway to commercialize the linear actuator through Variety Ability Systems Incorporated (VASI).

Powered Winch Unit. The powered winch unit also utilizes a commercially available motor/gear box combination. The motor is mounted to an aluminum housing and a shaft extension, integral with a worm, is attached to the gear box output shaft. The shaft extension is supported by an anti-thrust ball bearing to support axial loading in both directions.

The worm engages with a worm wheel, which is coaxially coupled to a small timing pulley. The worm

gear/pulley assembly is straddle-mounted in the aluminum housing by two ball bearings. A timing belt is threaded over the timing pulley and is secured by two fixed idler rollers located on each side of the pulley.

One end of the belt is attached to the housing, while the other end of the belt is attached to an appropriate point on the forearm. A limit switch triggered by the belt when the elbow is in full flexion, is provided as a safety feature. The unit is designed to be used interchangeably for the left or right arm of a powered orthosis user.

Myoelectric signals from the frontalis and procerus muscles are being used for control of the elbow and hand. The left and right sides are used for flexion and extension respectively. The user contracts the muscles on both sides of his forehead to switch between elbow and hand control.

Five individuals with ALS will be fitted with the powered orthosis. The usage of these devices will be monitored electronically with a miniature data-logging device. Subjects will be asked to fill out a questionnaire to evaluate the usefulness of the device for various functional activities and the cosmetic appearance of the device. A therapist will assess the subjects' ability to type, eat and manipulate objects with and without the device.

Results—This study is in progress and no results can be reported at this time.

[388] Development of a Water-Resistant Covering for AFOs During Recreational Activities

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Sponsor: *Hugh MacMillan Rehabilitation Centre, Prosthetic/Orthotic Service Department*

Purpose—The purpose of this research is to develop a durable and cosmetically appealing cover that provides protection and support for asensitive limbs and ankle-foot orthoses (AFOs) during recreational activities in and around the water. Abrasions from concrete and sand can develop into pressure sores, cause disuse of orthoses, restrict activities, increase deformity, and even necessitate surgical procedures.

Progress/Methodology—Five different prototypes underwent various static and dynamic tests on two

subjects. The final prototype design is now being tested on several subjects and will be assessed for durability, ease of application, cosmesis, functional ambulation, water, and sand resistance.

Future Plans—These covers will eventually become a marketable product available to all certified orthotists for fitting and dispensing.

[389] Development of a Powered Orthosis for Lower Limbs

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Purpose—In order to restore an appropriate gait pattern, a powered orthosis is being developed for paralyzed lower limbs that will support the patient's body and control lower limb movement. As a final goal, the powered orthosis will enable paraplegic patients to walk on level ground with a variable cadence, to stand and sit, and to go up and down a staircase by appropriate command.

Progress—Considering the results obtained experimentally through preceding years, a second prototype was designed and constructed. Its main purpose was to have a powered orthosis for lower limbs of an appropriate size, so that control methods explored in the past several years could be tested on paraplegic patients. The orthosis was fabricated in carbon-fiber reinforced plastic (C-FRP), and in thigh and femur parts, and four electrohydraulic actuators were incorporated. These actuators now have digital controls, in contrast with the first prototype which used an analog type. Each actuator is controlled by a single-board microprocessor, and all of these are totally controlled by a host microcomputer. Sensory systems such as foot-switch sensors to detect plantar contact, optical encoder to measure relative joint angle, and posture sensor to measure torso inclination in sagittal and frontal planes are used to accomplish a stable powered walk. The orthosis itself weighs 19.5 kg, and its control wagon 68 kg, which should be moved with the powered walk. A powered orthosis will be realized using these two components.

Preliminary Results—After having checked the basic function of the powered orthosis on a normal subject, it was tested on two paraplegics: both patients could walk with this powered orthosis, grasping the rail of the wagon for balance. This second version of the powered orthosis has sufficient torque for powered walk. After some modifications of the software program, one of the patients realized a powered walk at a cadence of 4.5 second/step, while the former cadence was 6.0 second/step.

Future Plans—Since the first tests on paraplegics have been successful, the control methods developed on the first prototype will be applied to the second prototype to improve the function of the orthosis. As two orthoses have been constructed which are identical except for geometrical size, all the control methods will be thoroughly tested on normal subjects prior to the clinical tests.

The interface between the patient and the powered orthosis should be improved for practical use of this device.

Recent Publications Resulting from This Research

Powered Orthosis for Lower Limbs. Miyamoto H, Ueda K, Sano A, Mori S, Nakajima I, Akamatsu N, Sakurai Y, in Proceedings of the 11th Biomechanism Symposium (SOBIM Japan), 221-230, 1989 (in Japanese).

Powered Orthosis for Lower Limbs. Miyamoto H, Sakurai Y, Nakajima I, Akamatsu N, in Proceedings of the 3rd French-Japanese Biomedical Technologies Symposium, 245-248, 1989.

[390] Development of a Practical, FES-Powered Walking Orthosis for Paraplegics

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Sponsor: Louisiana Board of Regents (LEQSF Grant)

Purpose—The purpose of this study was to develop the first practical, commercially available walking orthosis for paraplegics which could be used at home, without medical supervision and assistance, and at realistic metabolic energy cost to allow prolonged function in standing up, sitting down, and walking on flat and inclined surfaces.

Progress/Preliminary Results—The Louisiana State University reciprocating gait orthosis (LSU-RGO) powered with electrical stimulation of the thigh muscles was further developed to allow independent standing and walking on inclines at reduced energy cost. A large number of patients were fitted and followed up in the last 3 years.

Recent Publications Resulting from This Research

The RGO Generation II: Muscle Stimulation Powered Orthosis as a Practical Walking System for Thoracic Paraplegics. Solomonow M et al., *Orthopedics* 12:1309-1315, 1989.

Energy Consumption of Paraplegics Ambulating with the Reciprocating Gait Orthosis Powered with Electric Stimulation of the Thigh Muscles. Hirokawa S et al., *Arch Phys Med Rehabil* 71:687-694, 1990.

[391] Functional Biomechanical Characterization and Functional Design Specification: Orthotics

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Purpose—The objective of this project is to investigate the potential of orthotic devices to control the position/motion of the bones. The function of an orthotic device is to control, limit, or stabilize the position or motion of the skeletal structure. However, the intervening soft tissues between the orthosis and the bones of the skeletal system complicate this task.

By investigating the potential of an orthotic device to control the motion of the bones, we will determine bounds for the functional limitations and effectiveness of such devices. The emphasis of this study is on the knee joint and the potential for knee orthoses to control the relative motion of the femur and tibia.

Progress—The initial phase of this project examined the current practice of orthotic management of the knee joint. The intended function of knee orthoses may be broken into three categories: 1) skeletal stabilization; 2) motion restriction; and, 3) control of active motion. Skeletal stabilization devices, such as knee-ankle-foot orthoses, are used by persons with functional deficiencies who are unable to support their body weight on their legs. The success of a stabilizing orthosis is easy to judge: evaluate whether the human functional deficit has been compensated. The success of a motion restriction orthosis or motion control orthosis is more difficult to gauge and is the focus of this work.

A survey of orthoses for motion restriction and control was made, and revealed that a single method of attachment to the body is in common use: a proximal cuff for attachment to the thigh, a distal cuff for attachment to the calf, and a pair of hinges connecting the two cuffs together. The main difference between the motion control devices and the motion restriction devices is that the motion restriction orthoses employ limit stops on the hinges and, since restriction orthoses are primarily used post-traumatically and post-surgically, they incorporate thick foam pads between the orthosis and the leg. These pads are thought to exacerbate the problem of controlling bone motion, and therefore, the more tractable problem of the motion control orthosis is analyzed first.

Orthotic cuffs interface to the limb along the length of the thigh and calf, but the greatest conformity of the cuff geometry to the limb geometry is in the region of the knee joint and the anterior tibia. Conformity in these areas is intended to provide the best grip between the orthosis and the bone. However, due to the large degree of motion at the knee, the underlying soft tissue structures experience a high degree of spatial rearrangement (e.g., skin folding) when the knee is flexed or extended, and there is some question as to whether the orthosis is gripping the bones or gripping the mobile soft tissue. An experiment has been designed and is now being used to gauge the effects of tissue mobility around the knee joint.

[392] MED Arm: A Six-Degree-of-Freedom Orthosis Simulator for Tremor Research

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Sponsor: *National Institute on Disability and Rehabilitation Research; Burke Rehabilitation Center*

Purpose—The focus of this project is the design, fabrication, and testing of a 6-degree-of-freedom (DOF) computer-controlled energy-dissipating manipulum known as the MED (Modulated Energy Dissipation) Arm. Its function is to serve as a test bed for assessment of the effects of resistive loads on people disabled by movement disorders during functional whole-arm movements. The device may be viewed as a human-interactive orthosis-emulator which will allow experimental evaluation of the effectiveness of practical designs for tremor-suppression orthotics with a single laboratory facility. It is also expected to serve as: 1) a tool for objective measurement of tremors; 2) a differential diagnostic system; and, 3) a prototype compliant restraint system for tremor reduction in functional activities.

In its initial configuration, the MED Arm controls its magnetic particle brakes to behave as viscous dampers. Control of brake torque is open-loop, with the system's end-point 6-axis force/torque sensor serving only for data acquisition. The "shoulder" and "elbow" joints of the Arm are linked mechanically, effectively providing one rotational joint, and one prismatic joint. As a result of this, and the design of the three distal DOF, the forces and torques produced by the brakes all operate through a single end-point, and all act along and about respective orthogonal axes. It is this property that gives the system its force-velocity colinearity.

Progress—Fabrication and bench testing of the MED Arm have now been completed. A number of objective tests have been conducted to characterize the performance of the MED Arm. Results include the following: 1) the brakes used for the distal three axes produce a maximum force with which translations at the end-effector can be resisted of 14 lbf; 2) the measured maximum translational friction at the end-effector is 0.25 lbf or less depending on direction; 3) force-deflection characteristics at the Arm end-point with the brakes at maximum current to prevent slip showed a worst-case stiffness of 19 lbf/in;

and, 4) the Arm is completely counterbalanced so that no *weight* is perceived, only inertia. The effective passive inertia of the Arm at the end-point is 10 lbm or less, depending on the direction of applied force.

Methodology—The initial experimental protocol included two components described as Abstract and Functional. All parts of both protocols were performed at four levels of damping chosen to span the range of values provided by the Arm. In the Abstract tests, subjects were asked to observe a randomly moving target on a video screen and track it by movements of the Arm in a vertical plane aligned with the screen. For the Functional testing, a protocol was developed based on a standard clinical rating system. Activities performed by the subjects "wearing" the Arm included nose-to-finger tests, handwriting, Archimedes Spiral, water pouring, soup eating, and name-spelling on an expanded QWERTY keyboard.

Results—Preliminary human testing has been performed with three subjects, two tremor-disabled and one able-bodied, to begin evaluation of the effects of using the Arm. Data shows clear improvement with increased damping in the Functional test performance for both disabled subjects and a corresponding change in Abstract test results for one of them.

Future Plans/Implications—Experiments of the types described above will continue with additional subjects. Additional development tasks will be undertaken, including revision of the control algorithms to produce more sophisticated loading schemes. The effects on tremor of long-term use as a functional aid will also be measured.

Recent Publications Resulting from This Research

A Modulated-Energy-Dissipation Manipulator and Application to Suppressing Human Arm Tremor. Maxwell S, PhD diss., Massachusetts Institute of Technology, 1990.

[393a] Knee Flexion Alarm

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Sponsor: National Science Foundation

Purpose—Diseases that affect the peripheral nervous system (e.g., cerebral palsy), may only affect sensory feedback pathways rather than the entire system. For children in this situation, an appropriate feedback device can assist in proper walking without constant observation by another person. A student at the Caddo School for Exceptional Children has such perceptual problems, in addition to having very weak muscles. He often does not know where his body is in space; thus, he falls when he bends his knee beyond a certain angle. A knee flexion alarm device was designed for this student.

Methodology—The device requires two separate signals; one is a reference, the other corresponds to the flexion angle of the knee brace. By comparing the two signals, the device will signal the child when the proper condition is not present. With a variable reference to the angle of flexion at which the device signals the child, gradual training can be performed wherein the child learns, at his own rate, to maintain the proper knee position.

The circuit for such a device was built. The positive input is the reference voltage which can be set by adjustment of the 20 K-ohm potentiometer, each voltage corresponding to a particular angle. The negative input to the LM339 is connected to the 10 K-ohm potentiometer, which is mounted to a knee brace that the child wears. This voltage changes with the angle of the knee brace, which corresponds to the flexion angle of the child's knee. The 10 K-ohm potentiometer is connected so that as the flexion angle of the knee increases, so does the

voltage. Depending on the setting of the 20 K-ohm potentiometer, when the knee is flexed to an angle equal to or greater than necessary, the output of the LM339 drops enough to provide the required voltage across the piezoelectric buzzer to activate the buzzer, and the child hears an audible sound signaling that the knee is flexed too much. A switch allows the device to be turned off when needed, and an LED with a current-limiter resistor indicates whether the device is on or off.

The 10 K-ohm potentiometer is mounted to the knee brace. One part of the mounting holds the potentiometer and clamps to the upper part of the brace. The other part clamps to the shaft of the potentiometer and is strapped to the lower part of the brace. A cable runs from the potentiometer, terminating in a small box housing the circuitry, and worn on the child's belt. A belt clip mounted to the box allows the device to be worn without inconvenience or discomfort, yet allows for easy placement or removal.

Results—Whenever the student using this device hears a beep from the black box attached to his belt, he remembers to straighten his knee. This has allowed him to be more mobile and independent. The gait of this student also improved, because the alarm system helped him to increase knee extension during stance phase and he has learned to walk in a more erect fashion.

An electronic device has been built that, when attached to the long leg brace of a handicapped person with sensory deficit, provides an audio signal when the knees are in excessive flexion.

[393b] Upper Extremity Training Device

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Sponsor: National Science Foundation

Purpose—Some children confined to wheelchairs have difficulty using crutches or a walker due to an inability to support their body weight with their arms. With proper training, these children can learn to support themselves with their arms and eventually learn to use crutches or a walker. This transition from wheelchair to crutches or a

walker can be very beneficial to the child, allowing him to become more mobile and independent.

The purpose of this project was to design and build a device to measure the amount of vertical force a child applies while performing a shoulder depression motion. When the actual level of force being applied exceeds a

desired level preset by the therapist, the child receives reinforcement through the activation of a toy connected to the device. The therapist can increase the desired level until the child is able to apply enough vertical force to support his own body weight. After this goal is reached, the child can begin training in the use of crutches or a walker.

Methodology—The upper extremity training device consists of two force sensing plates (for the left and right sides), a control box for the therapist, and two stages of reinforcement.

Each force-sensing plate is constructed from one-quarter-inch aluminum tooling plate and contains a 200-lb load cell (A.L. Design, Inc., Model ALD-W-2) as the force transducer. The output of the load cell is fed into a three op-amp amplifier circuit. Two of the three op-amps provide high input impedance into the amplifier, and the third op-amp provides differential amplification of the two signals from the load cell. Since the voltage output of the load cell is proportional to the force being applied to it, an adjustable gain on the amplifier is required in order for the amplifier to maintain adequate

levels of output at low levels of input force. The amplified output from the load cell is compared with the potentiometer-controlled, desired-level set point using an LM339 comparator chip. When the actual level exceeds the desired level, the first stage of reinforcement is activated.

The first stage of reinforcement is simply an LED for each side. When the actual level from the load cell exceeds the desired-level set point, the comparator output goes to a “low” state and the LED lights up. When the actual load level exceeds the desired level on both sides, the second stage of reinforcement occurs.

Progress—A prototype model has been built and is presently being tested.

Future Plans/Implications—Actual use of this device cannot begin at the Caddo School for Exceptional Children until the beginning of the new school year. However, discussion with the physical therapist indicates that this device will be beneficial in teaching these children to support their body weight with their arms and eventually use a walker or crutches.

[394] CEDO: A Controlled-Energy-Dissipation Orthosis for Tremor Reduction in Activities of Daily Living

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Sponsor: *National Science Foundation; Burke Rehabilitation Center*

Purpose—People disabled by large amplitude pathological intention tremor (e.g., people who have multiple sclerosis or have had closed head injuries), are often incapable of undertaking activities of daily living independently in spite of normal strength. As a means of selectively suppressing relatively rapid oscillatory movements and exposing voluntary activity, these investigators have developed a 3-degree-of-freedom wheelchair-mounted compliant orthosis which dissipates energy in a frequency-dependent way. It has the approximate geometry of a standard commercial mobile arm support (“ball bearing feeder”), but incorporates computer-controlled magnetic particle brakes at each joint. The “elbow” brake is mounted on the support fixture and coupled to the joint by a parallelogram linkage in order to make it unnecessary for the user to move its mass when using the

device. The brakes are controlled to behave as viscous dampers whose damping constant is adjusted as a function of end-point position. Functional activities in a large part of the normal seated range of motion are permitted.

Progress—Experiments have been conducted with eight tremor-disabled patients to determine the short-term effectiveness of the CEDO in selective tremor reduction. These tests have included both simulated functional activities and objective tracking tasks. In virtually all cases, tremor was significantly reduced and signal-to-noise-ratio was improved (i.e., voluntary movement was attenuated less than tremor, if at all). Often, a value of damping was found between the extreme value and none which appeared to offer the optimal effect. The bulk of these tests were conducted at the Burke Rehabilitation

Center without on-site engineering involvement, indicating the reliability and user-friendliness of the device.

Future Plans/Implications—Experiments will continue, using the above protocol. In addition, tests of longer-term effects will be conducted since the system may be viewed as a resistive exercise machine. Further, an investigation of the effect on user performance of the system's force-velocity noncolinearity will be conducted. (The device geometry does not produce resistive force aligned with velocity at the user's arm for all end-point locations.)

Discussions are presently underway with an orthotics manufacturer with a view to licensing the design for marketing.

Recent Publications Resulting from This Research

Development of a Whole-Arm Orthosis for Tremor Suppression. Baiges IJ, Rosen MJ, in Proceedings of the 12th Annual RESNA Conference, New Orleans, 290-291, 1989.

Patents

Whole-Arm Orthosis for Damping of Tremor. Michael J. Rosen and Ivan Baiges, MIT Docket Number: MIT-5229. Patent applied for: June 25, 1990.

[395] Mobile Arm Support

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Sponsor: *None listed*

Purpose—This device provides a support for patients who have reduced arm control through neuromuscular weakness (particularly because of degenerative conditions like muscular dystrophy).

Methodology—The patient's arm is supported in soft slings above and below the elbow which allows for free movement in any direction—the volume of accessible space limited only by the patient. The patient's arm is weightless and therefore requires virtually no effort to move. The device can be adjusted to suit the arm weight of each patient individually. The benefits are patient independence and in the recreational and vocational areas. The use of physiotherapy is also promoted.

Progress—The device has progressed from a laboratory prototype to a production prototype and is being tested by patients at a local day-care center. The units can be wheelchair-mounted or floor-mounted as a workstation.

Preliminary Results—Patients who have used the arm support show an almost immediate change in mood because of their new ability. Range of movement, where any existed previously, seems to increase within minutes.

Future Plans—These devices will be produced inexpensively by a local company.

[396] Lifting Seat

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Sponsor: *None listed*

Purpose—This device assists patients to move from a seated to a full standing position.

Methodology—The patient is supported on a seat base which remains horizontal until the standing position. The seat armrests follow the movement, providing support

when the patient is upright, allowing easy transfer to a walking frame if needed.

The seat is raised using an airbag arranged in a novel way which reduces the pressure required and also keeps the pressure in the bag almost constant throughout the lift. The airbag is inflated by a vacuum cleaner motor and

could, for example, in a nursing home situation, be adapted to run from a compressed air system supplying many seats. The lift is entirely patient-controlled and can be halted at any stage.

Progress—A production prototype is being developed. Variations in form will be examined (i.e., a unit that can be slotted into a wheelchair or an armchair), or built into an armchair, etc.

Preliminary Results—The laboratory prototype could raise an 85 kg man to a fully standing position in approximately 5 seconds. This can be adjusted so that the rate at which a frail or nervous patient rises is limited. The potential maximum lift in this configuration, with the pump supplying 2.5 psi, was 170 kg.

XIII. Psychological and Psychosocial Disorders

For additional information on topics related to this category see the following Progress Reports: [1], [154], [168], [169], [172], [174], [175], [179], [188], [190], [263], [265], [267], [271], [431], [432], [433], [434], [435], [436], [437], [438].

[397] Effects of Expectation and Reward on Subtypes of Schizophrenia

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Sponsor: VA Rehabilitation Research and Development Service (Project #D515-RA)

Purpose—This research investigates the benefits of productive activity in the rehabilitation of patients with a diagnosis of schizophrenia. Key questions are: 1) Does greater expectation for productive activity lead to more productivity? 2) Does greater productivity lead to better rehabilitation outcomes? 3) Does pay act as a reward for schizophrenic patients in a work program leading to greater productivity, greater job satisfaction, and increased self-esteem? 4) Does greater expectation increase the likelihood of relapse and rehospitalization? and, 5) Are subtypes of schizophrenia based on psychological and neurobehavioral measures useful predictors of rehabilitation outcome?

Methodology—One hundred and fifty patients with DSM-III-R diagnoses of schizophrenia confirmed by SCID are being recruited from the general psychiatric service, stratified by prior work function and negative symptoms, and randomly assigned to one of three levels of expectation for work: 20 hours ("High Expectation," N=60), 10 hours ("Low Expectation," N=60), or no hours ("Self-regulation" control condition, N=30) of work required per week. All subjects are offered work through the Incentive Work Therapy (IWT) program. The IWT provides up to 20 hours of work per week in a variety of placements throughout the medical center with duties similar to those of regular hospital employees. All subjects attend weekly group sessions where, across all conditions of expectation, support is provided, level of expectation is reinforced, and weekly information on productivity and measures of clinical status (BPRS and PANSS) are obtained. Research staff evaluate productivity through on-site monitoring (Work Personality Profile), and supervisors complete biweekly

evaluations of performance (Minnesota Satisfactoriness Scale). Half the subjects receive weekly pay at \$3.40/hr for 6 months, and half are offered work without remuneration. Subjects are evaluated at baseline on demographic, neurobehavioral (negative symptoms, Wisconsin Card Sort, Continuous Performance Task, Thought Disorder) and productivity variables, and reevaluated at 6 and 12 months to assess clinical status, productivity, and other measures of rehabilitation outcome.

Progress/Preliminary Results—Rater intra-class R's for the PANSS (positive=0.76, negative=0.86, general=0.76), the BPRS (positive=0.79, negative=0.75, general=0.79), the WPP (mean=0.81), and the Gorham's Proverbs Thought Disorder Index (mean=0.91) have been determined. Forty-three subjects have entered the study in the first 10 months, 36 have been randomized, and nine have completed the 6-month intervention and follow-up evaluation. Of 16 patients assigned to work without pay, 13 (81%) declined to continue in the active intervention; of 21 patients randomized to pay conditions, only four (19%) have discontinued participation, suggesting that pay may be a robust predictor of work participation.

While analysis of main effects would be premature, some findings relating negative and positive symptoms to thought disorder and work performance emerge from baseline evaluations of subjects. Prominent negative symptoms (PANSS negative score >18) predict observed performance in the first week of work (multivariate $F=2.76$, $p=0.04$). Concrete thought disorder on the Thought Disorder Index is more prevalent in this sample of schizophrenic patients (50%) than is idiosyncratic and bizarre (positive) thought disorder (20%). Positive symptoms predict positive thought disorder ($r^2=0.10$, $p=0.04$),

and negative symptoms predict concrete thought disorder ($r^2=0.22$, $p=0.009$).

Implications—These preliminary results suggest that negative symptoms and concrete thought disorder are important dimensions to assess and address in schizophrenic patients referred for vocational rehabilitation. Eventual results will provide guidelines for expectation, reward,

and amount of activity in planning programs appropriate to the rehabilitation of schizophrenic veterans. We have created software which graphs weekly work performance and generates goal-setting recommendations. We have also produced manuals of group procedures for inducing various levels of expectation. These technologies may be easily transferred to other settings and used as clinical tools in the rehabilitation of veterans with schizophrenia.

[398] Psychiatric Rehabilitation in Nursing Homes

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Sponsor: VA Rehabilitation Research and Development Service (Project #D403-RA)

Purpose—Nursing homes are now the largest single place of care for the mentally ill, yet nursing home staff have had little or no training in working with psychiatric patients. Existing studies show deterioration in behavior of mental patients after nursing home placement when compared with similar patients randomly assigned to VA nursing care units or continued psychiatric hospitalization. In the face of further financial constraints and an aging population of patients, it is likely that even more psychiatric patients will be sent to community nursing homes. Many of these patients have a potential for psychosocial and functional rehabilitation, and in others, behavioral deterioration could at least be forestalled. Training and consultation for staff in nursing homes offers the potential for improving psychiatric care. The objective of this research is to test the effects of training and a cost-effective method of consultation for psychiatric rehabilitation in nursing homes.

Methodology—Nine nursing homes were randomly assigned to either a training program designed to increase staff knowledge and attitudes about caring for the mentally ill, or to control conditions. Following the training, mental patients admitted to the homes have been studied regarding behavioral outcomes at 6 and 12 months, as well as for whether treatment goals were attained. Half of the patients were randomly assigned to have their treatment goals discussed with nursing home staff so the effects of individualized feedback to staff about patients could be evaluated. If this study shows that the training feedback improves staff knowledge and attitudes as well as psychiatric patient results, then the method would be cost-effective for upgrading psychiatric services in nursing homes.

Preliminary Results—Effects of Staff Training. There were no significant differences between backgrounds of staff in trained versus untrained homes. Of the 203 trained and 191 untrained staff, only 4% were male, almost half (49%) were black, 48% were married, the average age was 39, and the mean years of education was 13. They had worked in the nursing homes about 2 years. There were positive changes for trained compared with control staff regarding some attitudes as measured by a 5-factor Opinions About Mental Illness Scale. At $p<0.001$, trained staff were less authoritarian, socially restrictive, and interpersonally sensitive. At $p<0.05$, mental health ideology was higher, but no change was found for the benevolence factor. Changes in attitudes measured by semantic differentials showed trained staff to have more favorable changes related to caring for the mentally ill ($p<0.001$), mental illness ($p<0.001$), the hostile patient ($p<0.001$), and the confused patient ($p<0.05$), with no changes related to the old, forgetful patient, and to old people. A Knowledge About Mental Illness Test showed trained staff to have more knowledge after training ($p<0.01$) than untrained staff. In summary, there were positive changes in attitudes and knowledge about mental illness at the end of training.

Preliminary Findings on Patients. A total of 223 patients were in the four groups of nine randomly assigned homes: Training and Consultation, Training Only, Consultation Only, and Control. Patients averaged 5.1 diagnoses. Only 2% had diagnoses of schizophrenia, 50% had organic brain disease, 30% were depressed, and 18% had other psychiatric diagnoses. Almost all (98%) had behavioral problems recorded. The average age was 79, 52% were female, and years of education averaged 11. The majority were white (88%), widowed (54%), and

listed children as next of kin (40%). The only background factor that differed significantly among the four groups of homes was patients with other psychiatric diagnoses ($p < 0.05$).

Future Plans—Data on behavioral changes of patients in the four groups will be analyzed during the next year.

[399] Change in Vocational Interests and Their Relationship to Adjustment After Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this longitudinal study is to examine the relationships between vocational interests, quality of life, and spinal cord injury (SCI) over time. The dual goals of this project are: 1) to generate longitudinal data on the stability and change of interests over a 10-year period after SCI for persons with varying ages at onset, time since injury, and severity of injury; and, 2) to identify relationships between interests and interest change with measures of quality of life (e.g., life satisfaction, problems, employment).

Progress—The original interests data was collected in 1980. At present, a second follow-up is being undertaken. Funding has been obtained and most administrative aspects of the study have been completed. Data collection is now being initiated.

Methodology—One hundred and seventeen spinal cord injured men who completed the Strong Interest Inventory (SII) in 1980 are being asked to complete a second SII, the NEO Personality Inventory, and a revised version of the Life Situation Questionnaire (LSQ). To identify the nature and stability of interests, descriptive statistics of the types of interests among the study sample will be computed. Stability coefficients will be generated among the study participants for the full sample, and among relevant subsamples of participants based on age at injury, time since injury, and severity of injury. The distributions of primary interests types will be cross-tabulated over the two occasions.

To assess the relationship of interests with quality of life, Pearson product moment correlations and the chi square statistic will be computed between SII scales and LSQ measures of quality of life; and multiple regression and discriminate analysis will be used to predict quality of life from 8 SII scales with separate equations generated using 1980 and 1990 SII scores. The squared

multiple correlations using the 1980 and 1990 SII scales as predictors will be compared to assess the relationship of interest change with quality of life. The Openness scale of the NEO will be correlated with interests change to determine its role as a variable in moderating changes.

Results—No data is yet available from the current follow-up. However, data from the earlier studies suggested that many of the activities and occupations which a large portion of individuals with SCI find interesting and rewarding may no longer be physically possible following SCI. Furthermore, retrospective research has suggested that these interests are unlikely to change after SCI. The current study will assess the amount of interest change of a 10-year period, factors mediating this change, and its relationship to quality of life.

Implications—If the interests of persons with SCI are not consistent with their physical limitations, to what extent and in what direction do they change following a period of time since injury? Are some persons, such as those with more severe injuries or those who were younger at injury, more likely to change their interest pattern? The question also arises as to the relationship between vocational interests and quality of life. Do persons whose preinjury interests patterns were in activities that are no longer physically possible have a lower quality of life than persons whose interests are compatible with their injuries? Lastly, among the individuals whose interests are initially incompatible with SCI, do persons who change their interests lead a higher quality of life than persons who do not change their interests? The answers to these questions will help rehabilitation professionals to understand the dynamics of adjustment and personality change after SCI that will be of great value when working with SCI clients.

[400] Relation of Substance Use to Rehabilitation Outcome in Persons with Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose/Progress—This is a prospective, 5-year project currently in its third year. At present, approximately 85 persons with spinal cord injury (SCI) have been recruited and have completed the initial assessment. This project is an elaboration on our earlier investigation of alcohol and other drug use before and after spinal cord injury. Specif-

ically, psychosocial aspects (i.e., coping skills, perceived social support, marital adjustment), are assessed, and a rehabilitation staff training component in identifying and referring individuals with histories of chemical dependence has been included.

[401] Psychosocial Aspects of Functional Electrical Stimulation

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Recent technological developments, such as functional electrical stimulation (FES), that allow standing or walking in persons with spinal cord injury (SCI), may dramatically improve current rehabilitation practices. However, behavioral medicine technology that can have such an impact on one's life, also has the

potential for creating negative psychological consequences. The objective of this project is to describe the psychological consequences of participation in FES research when outcomes are uncertain, and when persons see improved physical functioning as being critical to their well-being.

[402] A Description of Deaf Mental Health Service Clients Nationwide

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The goal of the study proposed here is to provide a picture of the deaf clinical population being provided mental health services. In general, we intend to gather information about their clientele from various agencies around the country providing mental health services to deaf individuals.

Methodology—The information will be collected in the form of a structured interview which elicits from a clinician descriptive data relevant to his or her client(s). The data will be of a range and degree of detail sufficient to allow the assignment of broad diagnostic category (i.e., affective disorder, schizophrenic disorder, anxiety disorder, character disorder, etc.) by the *Diagnostic and Statistical Manual of Mental Disorders*

(*DSM-III-R*) criteria. These interviews will be conducted by telephone and the data recorded on an interview protocol.

Implications—The proposed study is part of a larger project having a goal directly addressing an important research mandate, specifically, to provide a national database of information on mental health in deafness. The structured interview and protocol is intended to constitute the record format of an on-line database of client-based clinical information. A database to which mental health service providers can add clinical data, and from which agencies, clinicians, researchers, and others can search and extract clinical data would be a useful fulfillment of NIDRR's national database mandate.

[403] Longitudinal Changes in Adjustment After Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research (1973); Minnesota Medical Foundation (1984); American Association of Spinal Cord Injury Psychologists and Social Workers (1988)*

Purpose—The purpose of this research is to study the psychosocial, vocational, and medical adjustment of persons with spinal cord injuries (SCI) throughout the life cycle. The most important aspect of this study is the correlation of adjustment with length of survival.

Progress—There have been three stages of data collection thus far (1974, 1985, 1989), with the third stage just being completed. Data has been collected over a 15-year period, from 1974 to 1989.

Methodology—*Participants.* A longitudinal design was implemented to study life adjustment after SCI. Two samples were used in this study. Sample 1 began participating in 1974, whereas Sample 2 was added in 1985. Both samples were identified from case files of persons who had received urologic services at a large midwestern university hospital clinic prior to 1985. There were three screening criteria for inclusion to the study: 1) a traumatic spinal cord injury; 2) an injury of at least two years duration; and, 3) subject age of at least 18 years at the time of the study.

Procedures. The Life Situation Questionnaire (LSQ) was mailed to each person in Sample 1 in January and February of 1974. Two hundred fifty-six of a potential 301 respondents (85%) in Sample 1 returned usable LSQs in 1974. In 1985, a revised version of the LSQ was sent to all of the individuals who had participated in the 1974 survey (N=256) and to the second sample (N=266). A total of 347 participants returned usable questionnaires in the 1985 phase of the study (66%), 154 from Sample 1 and 193 from Sample 2. This response percentage is a lower limit estimate as 92 of the 1985 nonrespondents (18%) were either deceased (N=46), could not be located (N=31), or eliminated due to missing data (N=15).

The LSQ was revised for a second time in 1989 and sent to the 347 respondents from 1985. The Multidimensional Personality Questionnaire (MPQ) was added to the study. Two hundred and eighty-six of the potential 347 respondents returned LSQs in 1989 (an 82% response rate), 135 from Sample 1 and 151 from Sample 2. Forty participants were asked to complete a second set of

materials to establish the test-retest stability of the LSQ scales, with 31 responding an average of 102 days after completion of the original LSQ.

Instruments. The Life Situation Questionnaire (LSQ) was developed in 1974 to measure mostly objective information on a broad range of areas relevant to persons with SCI. The 1985 and 1989 revisions expanded the number of life satisfaction items (from 6 to 11 life areas), added a new set of 15 rating scales regarding problems, and incorporated a second set of activity items. The MPQ was developed for a nonpsychiatric population and measures 3 higher-order dimensions, 11 primary personality dimensions, and 6 validity indicators.

Results—Several significant findings were identified: 1) psychological, social, and vocational adjustment was correlated with length of survival; 2) level of productivity was related to positive personality traits (e.g., achievement); 3) adjustment remained stable over an 11-year period; 4) post-SCI adjustment was related to productivity; and, 5) the three underlying dimensions of self-reported problems were identified.

Implications—This research has been instrumental in validating the need for a comprehensive rehabilitation program by identifying key relationships between non-medical and medical outcomes (including survival). It has also established the stability of adjustment after long periods of time following SCI.

Recent Publications Resulting from This Research

- Concurrent and Long-Term Prediction of Self-Reported Problems Following Spinal Cord Injury. Krause JS, Crewe NM, *Int J Paraplegia* 28:186-202, 1990.
- The Relationship of Productivity to Adjustment Following Spinal Cord Injury. Krause JS, *Rehabil Counsel Bull* 33:188-199, 1990.
- Chronologic Age, Time Since Injury, and Time of Measurement: Effect on Adjustment After Spinal Cord Injury. Krause JS, Crewe NM, *Arch Phys Med Rehabil* (in press).
- An Eleven-Year Follow-Up of Adjustment to Spinal Cord Injury. Crewe NM, Krause JS, *Rehabil Psychol* (in press).
- Survival Following Spinal Cord Injury: A Fifteen-Year Prospective Study. Krause JS, *Rehabil Psychol* (in press).

[404] Psychosocial Factors in Adjustment of Bone Marrow Transplant Survivors

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Sponsor: National Cancer Institute, National Institutes of Health

Purpose—The major purpose of the study is to investigate the effects of the psychosocial resources that individuals bring to bone marrow transplantation (BMT) on their subsequent psychosocial adaptation and life satisfaction, and to examine how survivors change over time as a function of their personal resources, treatment experiences, and perceptions.

Progress—In November 1987, the research team began with a cross-sectional survey of all adult BMT survivors from the Johns Hopkins Oncology Center who were six months or more post-BMT and who were not in life-threatening relapse. This survey served as a pilot study for development of a prospective longitudinal study of psychosocial adjustment and quality-of-life of BMT survivors which was funded by NCI in 1989.

During the first year of this study, interviews and questionnaires were developed and are now being administered before BMT, and at three and six months post-BMT. Over 100 patients have been enrolled in the study, and other post-BMT interviews are scheduled and will be conducted at intervals of 12, 18, and 24 months with BMT survivors.

Methodology—A prospective longitudinal design is being employed that allows for tracking patients over time. The design calls for interviewing patients during the first days of their inpatient stays, before their transplant; interviewing patients during the latter portion of their third month post-BMT; and administering interviews and questionnaires to patients who return for their 6-, 12-, and 24-month physical exams. The same questionnaires are mailed to patients at 18 months post-BMT and to those who do not return for their exams. Because patients will enter the study at varying points in time, naturally-occurring cohorts will be created.

Preliminary Results—Based on the responses of 135 long-term survivors of BMT who completed a mailed survey questionnaire, a number of findings have been described in initial project papers. The respondents to the survey represented 86% of eligible subjects contacted

and had survived for 6 to 149 months (mean=47 months). Some of these results are as follows:

1. Among long-term BMT survivors, being able to retain valued roles was found to be significantly related to higher quality of life. The roles of worker, home maintainer, friend, and family member significantly increased in their perceived importance for those who were able to retain them after BMT.

2. Regarding employment status of these long-term survivors, 65% had returned to full or part-time employment and one-third of those not employed were attending school. Job discrimination was reported by 23% and problems obtaining insurance were reported by 43%.

3. Health and functional status were also assessed in this group of adult BMT survivors. Most (93%) were able to perform normal activities with minor or no physical problems. Self-reports of health and function were highly significantly correlated with professional ratings of functional status.

Future Plans—During the second year of the study, the research team will continue to implement its prospective longitudinal study by enrolling new patients coming for BMT into the study cohort, and following those who survive by obtaining data from them at 3, 6, 18, and 24 months. Family members or those other individuals close to the patients who continue to act as nonprofessional caregivers will also be given interviews and questionnaires at the various data collection points over the two-year period. Analyses of preliminary available data will continue as a means of assessing the effectiveness of current measures and as a basis for identifying the need for further data collection and study refinement.

Recent Publications Resulting from This Research

Self-Concept and Cancer in Adults: Theoretical and Methodological Issues. Curbow B, Somerfield M, Legro M, Sonnega J, Soc Sci Med 31:115-128, 1990.

Role Retention and Quality of Life of Bone Marrow Transplant Survivors. Baker F, Curbow B, Wingard JR, Soc Sci Med (in press).

Use of the Rosenberg Self-Esteem Scale with Adult Cancer Patients. Curbow B, Somerfield M, J Psychosoc Oncol (in press).

[405] Neuropsychological Testing of Children and Adults with HIV Disease

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Sponsor: *National Cancer Institute, National Institutes of Health; Medical Illness Counseling Center, Chevy Chase, MD*

Purpose—The purpose of these studies is to investigate how the HIV infection may compromise the central nervous system and may result in significant deficits in cognitive, affective, motor, and psychosocial behavior. In addition, the potentially beneficial effects of antiretroviral therapy on these behaviors is evaluated.

Methodology/Implications—Several of our studies have indicated that therapies which are effective against HIV replication, and thus may remove some of the HIV burden on the central nervous system (CNS), may also improve neuropsychological functioning and adaptive behavior both in children and adults.

In children, significant improvements in cognitive and intellectual functional, as well as adaptive behaviors such as socialization, communication, and daily living skills have been observed.

Comparison of the effectiveness of treatment with AZT either intravenously on a continuous infusion schedule, or oral on an intermittent schedule, with ddC (2',3'-dideoxycytidine), or with ddI (2',3'-dideoxyinosine) has shown significant variability in response. Overall, these differential effects on CNS functioning may indicate differences in CNS bioavailability of the compounds or their active metabolites and/or specific effects on

neurotoxic cytokines of HIV by these antiretroviral agents. On an individual basis, however, with each of the above-mentioned therapies, some patients have shown remarkable improvements in functioning, well beyond possible practice effects. The large degree of variability in response to antiretroviral agents indicates the need to search for prognostic factors and possible patient subgroups which can explain the differential efficacy.

Recent Publications Resulting from This Research

Dideoxycytidine Alone and in an Alternating Schedule with Zidovudine (AZT) in Children with Symptomatic Human Immunodeficiency Virus Infection: A Pilot Study. Pizzo PA et al., *J Pediatr* (in press).

Effect of Continuous Infusion AZT Therapy on Neuropsychological Functioning in Children with Symptomatic HIV Disease. Brouwers P et al., *J Pediatr* (in press).

Organ Specific Complications: Central Nervous System Involvement: Manifestations and Evaluation. Brouwers P, Belman A, Epstein L, in *Pediatric AIDS: The Challenge of HIV Infection in Infants, Children and Adolescents*, P.A. Pizzo, C.M. Wilfert (Eds.). Baltimore: Williams & Wilkins (in press).

The National Cancer Institute Phase I Study of ddI in Adults with AIDS-Related Complex: Analysis of Activity and Toxicity Profiles. Yarchoan R et al., *Rev Infect Dis* (in press).

Treatment of HIV Infection with 2',3'-Dideoxyinosine (ddI): Long-Term Activity/Toxicity Profile and Effect on HIV-Dementia. Yarchoan R et al., *Lancet* (in press).

[406] Patient Perception of Blood Glucose Levels

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Sponsor: *National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; University of Virginia*

Purpose—Previous studies have demonstrated considerable variability in the ability of some individuals to perceive their blood glucose (BG) level, and to some extent, to counterregulate it. It has also been observed that the metabolic status of some individuals is quite sensitive to psychological stress.

This study has been assessing the ability of some persons with Type I diabetes to perceive their own BG levels, testing strategies for improving this ability in

others, and measuring the blood glucose response to psychological and hormonal stressors.

Methodology—Over a period of 5 years, 80 subjects will be assessed in terms of ability to identify BG-relevant cues and BG level, therapeutic adherence, and various diabetic-relevant psychological variables. They will be hospitalized to assess BG response to psychological and hormonal stressors, and ability to counterregulate during

insulin infusion. Three treatment groups will be formed: 1) to evaluate two different techniques to improve the subjects' ability to perceive BG level, and the impact of this improvement; 2) to evaluate relationships of stress and BG level, and differences in vulnerability to stress; and, 3) the effects of steady insulin infusion via an insulin pump on BG reactivity to stress.

Future Plans/Implications—The ability to differentiate groups of diabetic individuals on the basis of metabolic reactivity to stress promises to be of use in patient management. If techniques can be found which will improve patient perception of BG levels, this may help patients improve their self-care decisions.

[407] Physiological and Psychological Mechanisms for Irritable Bowel Syndrome

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Sponsor: *National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; Johns Hopkins University*

Purpose—This study seeks to further differentiate persons who have irritable bowel syndrome (IBS) into two groups (as previously hypothesized) on the basis of physiological data and behavioral investigations—those whose problem is fundamentally physiological, and those whose problem appears to be fundamentally psychological. The study will also compare the psychological profile of persons with IBS who have consulted a doctor with those who have not.

Methodology—Physiological measures of bowel activity will be made: the incidence of colon slow waves greater than or equal to 15 seconds in duration, contractile activity in the colon over 24 hours, and the number of peristaltic contractions in 24 hours. These will be combined with psychometric inventories, an assessment of the relationship of stressful life events to exacerbation of bowel symptoms, and a questionnaire

about medical clinical visits and medical disability days over one year.

Preliminary Results—It appears that persons with IBS should be categorized into two groups, determined by the physiological or psychological basis of the problem. It also appears that the occurrence of diarrhea or constipation is not indicative of a person's likelihood of belonging to one group or the other.

Future Plans/Implications—Differentiation between these two groups of IBS patients has important implications for the differing treatments which may prove to be appropriate for each. Refinement of the measures under study may provide a diagnostic tool more widely usable, or may point the way toward development of more effective diagnoses. After differential diagnosis is achievable, the possibility of effective treatment will be increased.

[408] Patterns of Eating in Lean and Obese Humans

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Sponsor: *National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health*

Purpose—The long-term objective of this proposal is to take information gained from laboratory studies of the variables that control food intake and apply it to the treatment of obesity.

Methodology—We will study the microstructure of eating behavior (chewing, palatability), electromyographic (EMG) recording of chewing, and ambulatory monitoring

of chewing. The investigators will also test whether behavioral changes advocated by treatment programs for obesity, such as slowing the rate of ingestion, actually help people to eat less, and will differentiate between the eating behavior of lean and obese people.

Preliminary Results—1) EMG studies show that when food is relatively easy to chew, increasing the bite size

increases the rate of intake at the beginning of the meal, but does not necessarily increase the total amount eaten; 2) two laboratory studies on eating patterns of nondieting lean and obese subjects have been conducted. One result was that obese subjects select flavors to maximize palatability throughout a meal more than normal-weight subjects do; 3) a study showed that a gastric balloon has limited usefulness in the treatment of obesity; and, 4) slowing the rate of intake was *not* necessary to lose weight.

Future Plans/Implications—Groundwork necessary to develop an ambulatory system to monitor chewing has been done. Development of ambulatory monitor itself continues.

Investigators will determine whether behavioral measures help predict the outcome of treatment and whether certain behavioral changes can either promote or interfere with weight loss. They will also test whether weight loss causes changes in the behavioral measures. Given the fact that most people who lose weight will regain all or most of it, it is extremely important to optimize the treatment of obesity by tailoring weight-loss regimens to individual patients.

Recent Publications Resulting from This Research

Sugar and Fat: Sensory and Hedonic Evaluation of Liquid and Solid Foods. Drewnowski A et al., *Physiol Behav* 45:177-183, 1989.

[409] Neuroanatomical Asymmetry and Psychological Characteristics

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The aim of this research is to ascertain whether asymmetry in the gross morphology of the right and left temporal lobes in the human brain is related to functional asymmetry. Asymmetry has been documented in the planum temporale (the posterior part of the superior surface of the temporal lobe). Specifically, the research aims to establish whether the more prevalent pattern of a larger left planum is a substrate of left hemisphere representation of language functions. To do this, seriously ill cancer patients are recruited who are willing to take an extensive battery of neuropsychological tests, and to consent to a postmortem examination in the event of death. The aim is to study 60 cases with both psychological and anatomical measures.

Methodology—Measures of the planum temporale will be studied in relation to the test scores, as will other anatomical measures, including Broca's region and the corpus callosum. The purpose of the research is also to study whether there are any neurohistological differences between the hemispheres that could be a basis of functional asymmetry. At least 16 specimens will be studied in one particular cytoarchitectonic region of the planum; the cases will be selected to vary in planum asymmetry,

sex, and hand preference. Cortical thickness and various cell counts will be obtained from Nissl-stained sections. The histological measures will be compared with the gross morphology and psychological scores. Histological analysis will also be done in Broca's region and the corpus callosum. The work involves the disciplines of cognitive neuropsychology and neuroanatomy, as well as extensive organization to coordinate the efforts of various groups, including oncologists, hospital staff, community physicians, pathologists, and research staff.

Implications—It is anticipated that this research will contribute theoretically to the biological basis of cerebral dominance and to the neural mechanisms of cognition. It may have relevance to the study of individual differences in cognition and brain organization, to the variation in the cognitive deficits and recovery subsequent to brain damage, and to etiological factors in some neuropsychiatric disorders that may involve atypical patterns of functional asymmetry. Finally, the method of this research may serve as a prototype for the study of other brain-behavior issues in normal and disordered populations requiring testing before and after death.

[410] Program in Cognitive Neuroscience

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—This proposed project in cognitive neuroscience has as its aim the multidisciplinary study of human perception, cognition, and motor function. It is our belief that while it is important to establish relationships between mental functions and particular brain structures, it is equally important to understand how such localizable functions interact in the control of behavior.

Methodology—A range of mental functions, including language, attention, auditory pattern recognition, memory,

and motor control will be studied in normal and special neurological populations. Studies in these areas have been designed to examine specific psychological functions, as well as the roles these specific functions play in more general behavior. Our structural approach, on the other hand, includes metabolic analysis with positron emission tomography, structural analysis with computerized tomography, and electrophysiological analysis with event-related potentials. These activities are all presently being pursued.

[411] Cognitive Control of Movement (Human)

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Our purpose is to intensify and expand the basic research on the cognitive events that precede and allow for the performance of voluntary movements, and apply the research to the analysis of movement disorders.

Methodology—Five projects will be pursued: 1) Planning of aimed hand movements. The aim of this new experimental procedure is to determine how people plan a series of aimed hand movements immediately after seeing a display specifying the targets to which movements must be aimed; 2) Cognitive control of movement sequences. This consists of two parts: the three-dimensional analog of project (1) above, where the focus is on planning reaching and manipulation, both in normal and clinical (especially apraxic) populations, and analysis of two recently discovered motor “illusions” that shed light on the mechanisms of serial ordering of behavior;

3) Internal representation of the body surface. By having subjects perform a new speeded discrimination task in which all possible pairs of test sites serve as targets and distractors, the data can be analyzed with multidimensional scaling to allow for “visualization” of the body representation. Pilot work has turned up effects of handedness and posture; 4) A textbook, *Human Movement Control*, will be written. The book will provide an overview of research and treatment pertaining to each of the major activity systems (e.g., walking, looking, speaking, writing, reaching, and grasping); and, 5) Cognitive Darwinism. Darwin’s theory of natural selection will be applied to cognitive function.

Implications—The key notion is that spontaneous variation in cognitive structures may provide a basis for generalization, preparation, and other important phenomena.

[412] Anatomical Substrates of Complex Behavior

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Sponsor: National Institute of Neurological Disorders and Stroke, National Institutes of Health

Purpose—The primary goal is to further elucidate the relation between brain structure, conceptualized as network systems of neural units, and cognitive processes traditionally studied in the disciplines of behavioral neurology, neuropsychology, cognitive science, and linguistics. The cognitive domain under scrutiny encompasses vision, memory, language, and executive control.

Methodology/Implications—The principal subjects for the study are human beings who have sustained focal brain damage as a result of neurological disease or surgical ablation, although in one of the projects, nonhuman primates are utilized in anatomical investigations. In three of the projects, regions of interest in brains of patients with Alzheimer's disease will also be studied anatomically.

The approach encompasses: 1) experimental neuropsychological, psychophysical, psychophysiological, and related assessment techniques; 2) human neuroanatomical techniques, including neuroimaging methods such as computerized tomography (CT) and magnetic resonance (MR), as well as the study of postmortem cerebral tissue; and, 3) neuroanatomical tracing techniques in experi-

mental animals. The distinct aspects of the methodology relate to an experimental, basic science attitude toward clinical material, and to a strong interaction between basic and applied neuroanatomy, and between anatomical and cognitive data.

The detailed understanding of the organization of the neural systems that subtend vision, language, memory, and executive control is a desirable goal. It provides crucial constraints in the evolving research models of mind and brain relationships, and contributes to clinical neurology, by providing new knowledge pertinent to cerebrovascular disease, Alzheimer's disease, and related conditions. Such knowledge is important for the improvement of diagnosis and for the development of new remediation strategies in patients with acquired cognitive impairments (it is especially important regarding Alzheimer's, because the anatomical elucidation we have been developing can provide clues to potential mechanisms of the disease). The project is meant to bring human neuroanatomy closer to nonhuman primate neuroanatomy and to promote the integration of data derived from neuropsychological and neurological studies in the body of neurophysiology and neuropathology.

[413] Secondary Complications and Adjustment in Spinal Cord Injury

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Sponsor: Shepherd Spinal Center

Purpose—The purpose of this study is to develop a self-report database on a wide range of psychological, social, and vocational variables using a large sample of spinal cord injured (SCI) outpatients. This database will be used to meet the following objectives: 1) provide validity data on the Life Situation Questionnaire (LSQ); 2) generate data on a Southeastern sample that can directly be compared with similar data from a Northern sample; 3) provide prospective data to identify predictors of important future health-related problems such as mortality, decubitus ulcers, urinary infections, and other health problems.

Progress—The participant sample (N=500) has been identified. Key personnel are being hired. Revisions have been made to the LSQ in preparation for initiation of data collection.

Methodology—Participants. All participants were identified from case files of former Shepherd Spinal Center patients. The three screening criteria for inclusion in the study were: 1) a traumatic spinal cord injury; 2) an injury of at least two years duration; and, 3) subject age of at least 18 years at the time of the study.

Design. Data on a wide range of psychological, social, and vocational variables are being collected from all participants. In addition, extensive information on secondary complications and activities of daily living (ADL) is also being collected. In order to develop reliability data, a random subsample of 60 participants will be selected. The LSQ will be readministered to this group. These data will be used retrospectively to determine predictors of future preventable secondary complications (e.g., decubitus ulcers, rehospitalizations).

Instruments. The LSQ was developed in 1974 to measure mostly objective information on a broad range of areas relevant to persons with SCI. The 1974 version contained items on basic demographic and injury-related variables, employment, activities, recent medical history, self-rated adjustment, and life satisfaction. Later revisions added more items on life satisfaction, self-reported problems, and activities. The present revision maintained most previous items, but expanded the coverage of secondary complications.

Data analysis. Descriptive statistics will be developed from all data gathered from the sample. Factor analysis will be used to define homogeneous items for scale development. The reliability of these scales will be determined by generating test-retest stability coefficients and alpha coefficients.

Future Plans/Implications—In 1992, the LSQ will again be sent out to the study participants. Secondary complications will be assessed and predictors of these complications will be identified using the current database.

This study will provide researchers and practitioners with a standardized measure of adjustment after SCI, identify geographic differences in SCI outcomes, and identify important longitudinal predictors of persons at risk for secondary complications after SCI.

Recent Publications Resulting from This Research

The Relationship of Productivity to Adjustment Following Spinal Cord Injury. Krause JS, Rehabil Counsel Bull 33:188-199, 1990.

[414] Effects of Active Recreation Participation on Psychological Adjustment and Social Integration of Spinal Cord Injured Patients

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Sponsor: Shepherd Spinal Center

Purpose—The purpose of the study is to identify the quantitative effects of an active recreation program on selected variables that indicate psychological adjustment of the spinal cord patient. The active recreation program exposes the patient to activities that test his/her capabilities and focuses on individual potential rather than limitations. Examples of activities included in this category are: canoeing, water skiing, camping, wheelchair sports, scuba diving, etc. Through the utilization of the Attitude Toward Handicapped Individuals, the Rotter Locus of Control Scale, and the Coopersmith Self-Esteem Inventory Adult Form, the study will determine if these areas are affected by active recreation participation. An instrument developed in-house will also measure leisure patterns, social patterns, and secondary complications reported 1-year postdischarge.

Progress/Methodology—Sixty experimental group subjects participated in the active recreation program

and were compared with 60 patients who did not participate. Experimental and control group subjects were tested (pretest) one week prior to participation in their first active recreation activity. The post-test was administered to patients in both groups one week prior to discharge. Follow-up testing is being administered to patients in each group by phone 9 months to 1 year following discharge. The follow-up instrument reflects leisure activities pursued, participation levels, times left home per week, barriers to social integration, and basic health information (secondary complications).

Results—Results, available later this year, will reflect differences in the experimental and control groups on the three instruments listed, as well as medical complications, times left home per week, and leisure participation rates 1-year postdischarge.

[415] Nutritional Education Program for Schizophrenic Outpatients

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Sponsor: *Tayside Health Board; Professor Dott Memorial Fund*

Purpose—This study investigates the hypothesis that introduction of a once-weekly nutritional education package over a period of 6 weeks will improve the shopping and eating habits and knowledge of healthy eating of chronic schizophrenic day hospital attenders.

Methodology—An experiment was carried out over 8 weeks to test this hypothesis. Eleven chronic schizophrenics were subjects for a study which asked three research questions: 1) How do these individuals with a chronic mental illness function as deinstitutionalised persons? 2) Does participation in a 6-week nutritional education program affect cognitive performance and behavior? and, 3) Does the nutritional education package require further refinement?

Results—This experiment produced qualitative data which have been analyzed using descriptive statistics and evaluation of questionnaires. The pre- and post-testing of the subjects suggest that improved nutrition knowledge does not relate to attitudes or to shopping and eating behavior of chronic schizophrenics living in the community.

Future Plans/Implications—In acknowledging that the results tentatively support the cognitive component of the hypothesis, a 6-month follow-up study is indicated to investigate whether these improvements have been maintained. Moreover, it is often assumed that a change in behavior is the result of a change in knowledge, with the action mediated by a change in attitude. In this study, the evidence for that proposal is not very good. Subjects with high nutrition knowledge scores, in the main, have not reported a change in behavior.

One possible problem with this study may be that nutritional knowledge is related to general attitudes toward nutrition but not to more specific attitudes toward the eating of certain foods. That explanation could account for the lack of clear relationships between nutritional knowledge and the consumption of specific foods.

Accordingly, further modification of the questionnaires is indicated.

In disproving the assumption that healthy food and nutrition-related behavior is associated with improved nutritional knowledge, the indication is that behavior is influenced much more strongly by other factors. This finding suggests that the educational component within the package plays a minor role in promoting change. Furthermore, while it is generally believed that successful living skills programs have the common characteristics of intensive treatment and training within a real-life context, a particular area for future research must be the elucidation of what other factors motivate chronic schizophrenic day hospital attenders to generalize nutritional education skills training and adopt more healthy life-styles. Indeed, a major issue for the Occupational Therapy profession to resolve is that of providing effective services to mental health patients in the most appropriate location.

In this investigation, for example, where reported satisfaction among the group is high, it is apparent that the day hospital is an ideal setting for genuine social psychiatric care. Clearly, the chronic schizophrenics in this study must value what they are offered. Indeed, they may value it so much that they do not want to be discharged. Consequently, dependence on services is one of the major dilemmas of rehabilitation practice.

The final words in this study must reiterate that these results apply to one particular setting; since alterations in staff or in other variables connected with treatment might have led to different results, the extent to which it is possible to generalize is limited. Yet, the data produced by this small study are plentiful and confirm that it is a fertile area for future research.

Patent Pending

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England, UK.

Awards

British Dietetic Association Healthy Eating Awards, First Prize,
Hospital Sector, 1989.

XIV. Sensory Aids

For additional information on topics related to this category see the following Progress Reports: [178], [244], [402], [539].

A. Hearing Impairment

[416] Computerized Adaptive Methods for Selecting Hearing Aids

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C432-RA)*

Purpose—The general purpose of these experiments was to explore critical variables which govern the choice of frequency-gain characteristics preferred by individuals with hearing impairment and to investigate the potential use of adaptive test strategies for their use within the hearing-aid selection process. Data were obtained in studies in which comparisons were made between the preferred frequency-gain characteristics chosen with a two-dimensional (2-D) (two-band) simplex adaptive procedure and those obtained with a three-dimensional (3-D) (three-band) simplex adaptive procedure. The comparison between results from a two-channel versus a three-channel system are especially relevant since two-channel compression systems are now commercially available for both in-the-ear and behind-the-ear hearing aids.

Methodology—The adaptive test strategies were administered via a computer-controlled master hearing aid system. The experimental speech signal (connected discourse for these studies) was presented to the subject seated in a double-walled acoustic chamber. The subject wore a behind-the-ear hearing aid with a front-facing microphone. Following preamplification, the signal was routed through a digital filter system with appropriate A-D and D-A filters. The characteristics of the digital filters, which shape the signal, were varied by a manual switch (via a computer) controlled by the subject. The shaped-speech signal was directed through a receiver, located in the shell of the hearing aid, and via tubing and an earmold tailored for each subject's ear.

Variations of the simplex adaptive test strategy, incorporating a paired-comparison technique, was the basic method utilized to accomplish the experiments. The center cell of the simplex procedure was programmed to provide the frequency gain characteristics predicted by the National Acoustic Laboratory (NAL) prescription procedures for each individual subject. The frequency gain characteristics in the remaining cells of a 5×5 simplex varied systematically regarding the NAL frequency response (center cell) over a 24 dB range (± 12 dB). A probe-microphone system was used to monitor the insertion gain for the center cell (starting point) of the simplex, and for the winning cell containing the preferred frequency-gain response.

Progress—Ten hearing-impaired subjects (five with steep high-frequency loss, and five with relatively flat audiogram) gave preference judgments for both a 2-D (low and high frequency band divided at 1,200 Hz) and a 3-D (three bands, 200-600 Hz, 600-2,000 Hz, 2,000-5,000 Hz) strategy. In the first experiment, subjects listened to continuous discourse delivered at an overall RMS level of 65 dB in quiet, while in a second experiment (currently in progress), subjects listened to the speech in a background of traffic and party noise.

Preliminary Results—Results indicate that subjects generally made similar preference judgments for both the 2-D and 3-D strategies. However, several subjects with steeply-sloping high-frequency hearing loss consistently

preferred more gain in the mid-frequency region, selectively available only in the 3-D strategy. In addition, the average preferred insertion gain for the groups was similar to that recommended by the NAL prescriptive procedure, although the variability of the insertion gain among the listeners was high. Currently, six hearing-impaired listeners have performed the 3-D simplex procedure in quiet, and in traffic and party noise. No clear differences in preferred frequency-gain responses

have been found when listening in noise (levels limited to 65 dB) or quiet.

Recent Publications Resulting from This Research

Application of Simplex Adaptive Test Strategies for Hearing Aid Selection. Dirks DD, Noffsinger PD, poster session at the American Speech and Hearing Association, Seattle, WA, 1990. Frequency-Gain Shaping for Hearing Aids. Dirks DD, Noffsinger PD, invited paper, presented at the Conference on Issues in Advanced Hearing Aid Research, Lake Arrowhead, CA, 1990.

[417] Validity and Reliability of a Physiological Test of Vestibular Function

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Sponsor: VA Rehabilitation Research and Development Service (Project #C412-RA)

Purpose—Balance and movement disorders associated with the inner ear are common medical complaints, affecting approximately 40% of the population over 40 years of age. There is a need for a well-documented vestibular test that is comfortable to the patient, simple to implement, provides useful diagnostic results, and is relatively inexpensive and fast to administer.

Methodology—A computer-based technique has been developed by the co-principal investigator, Dr. Dennis O'Leary, to fulfill these needs. The technique, which is called the Vestibular Autorotation Test (VAT), monitors the horizontal and vertical vestibulo-ocular reflexes (VOR) in the 2-6 Hz physiological range using 18 seconds of horizontal or vertical movement with the eyes fixed on a stationary target. Eye position and head velocity information, calculated from eye position information using a two-point central difference deviate algorithm, and head velocity data are reduced to 100 samples/s from which VOR gain (eye velocity amplitude/head velocity amplitude) and phase are computed by discrete Fourier analysis, using signal processing techniques on a personal computer.

For the VAT to be developed as a routine clinical procedure, which potentially could replace current electronystagmography (ENG) techniques including the caloric, tracking, and rotatory chair procedures, a broad normal database including all age groups was needed to

establish the validity and reliability of the VAT. The following questions were addressed in the 3-year study: 1) Does the VAT provide a valid and reliable assessment of vestibular function? 2) Are the data provided by the VAT more sensitive to vestibular dysfunction than are the data provided by the currently used ENG techniques? and, 3) Is there a parallel age-related decline in vestibular and auditory function that can be measured with the VAT and with traditional auditory tests?

Results—More than 100 subjects with normal hearing sensitivity for their age, and no vestibular complaints, were evaluated with the VAT. Normative data obtained within this lab did not fall within the standard deviations developed from normative data obtained in the vestibular lab at the University of Southern California. These differences may be the result of different populations and/or methodology. In addition, four subjects with confirmed diagnosis for acoustic neuroma were compared to the normative data, but produced no consistent abnormality.

Future Plans—Further evaluation of normal subjects, with the VAT, will continue at this site in an effort to expand the database. Ongoing investigation in the area of vestibular research, with the possible outcome of a valid and reliable test of vestibular function, will continue to be a primary goal of this laboratory.

[418] Auditory Prosthesis for Sensorineural Hearing Loss

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Sponsor: VA Rehabilitation Research and Development Service (Project #C054-3RA)

Purpose—The object of this research is to determine the optimal design parameters and fitting procedures for a new multichannel compression hearing aid for patients with sensorineural hearing loss (SNHL). Previously, we have demonstrated that an initial 8-channel version of the aid was very effective in helping individuals with SNHL to recognize speech sounds in the presence of noise—a key problem for SNHL patients. The present work will include a systematic study of the following parameters of the multichannel compression hearing aid: 1) number of channels; 2) time constant of the compression; 3) location of the channel boundaries with respect to the configuration of the hearing loss; 4) limit of compression range; and, 5) shape of the compression function. The present work will also examine the importance of learning to use a multichannel compression hearing aid—aspects of the previous results suggested that the performance of the subjects with the new aid had continued to improve throughout the study, over 40 hours of testing per subject.

Progress—The performance of the multichannel compression aid improves as the number of channels increases, up to 8 channels; then the performance is essentially constant from 8 to 16 channels. The performance of the aid is quite insensitive to the time parameter (for time windows of 5 to 200 ms) unless the noise background is modulated in time; with modulated noise, there is a small but statistically significant advantage for moderately long (40 ms) time windows. Concentrating narrower frequency

bands (one-quarter octave as opposed to three-eighths and one-half octave), just below the frequency region where the subject's hearing loss becomes severe, yields optimal performance with our multichannel compression system. Included in two of the above experiments was a noncompression aid which was fitted by a standard research method; performance with this aid was inferior to that with multichannel compression, especially at lower signal-to-noise ratios (S/N). For each parametric experiment, nonsense syllable recognition performance was measured in 15 SNHL subjects at 5 S/N with both a male and female voice. At this time, we have begun to measure the effect of the limit of the compression range.

Preliminary Results—The effect of limiting the range of compression has been measured in only a few subjects. Those subjects with the most severe hearing losses seem to need full range compression. Subjects with less severe losses, however, showed improved performance when the range of compression was reduced by 10 or 20 dB.

Future Plans—Further data analysis and other experiments with lower intensity stimuli must be done to fully evaluate the effect of the range of compression.

Recent Publications Resulting from This Research

Effect of Number of Channels on the Performance of a Multichannel Compression Hearing Aid. Yund EW, Buckles KM, J Acoust Soc Am (Suppl 1)85:S27, 1989.

[419] Variables Affecting Hearing Aid Performance

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Purpose—The overall objective of this project is to study aural-acoustic source and load impedance relationships which underlie contemporary hearing aid fitting procedures.

Progress—For normal and pathologic subjects, ear canal and volume data and eardrum impedance data are

being studied. Further, the effects of dc pressure differences across the tympanic membrane, aural pathology, and the acoustic stapedial reflex on probe microphone observations of sound spectra and on the transfer of energy through the middle ear are being assessed.

Transducers having high and low acoustic impedance are being used to deliver acoustic stimuli to different acoustic loads. The effect of the interaction of these are being studied by probe tube-microphone, auditory threshold studies, and word recognition studies.

A personal computer-based measurement system has been developed to acquire and calculate both acoustic source and acoustic load impedance quantities. Work toward developing a clinically feasible yet accurate method of determining the geometry of the ear canal continues. In validation of the measurement system, 1) studies have been completed which showed good agreement between measured and calculated quantities for cylindrical cavities; 2) test-retest studies show good agreement; and, 3) measured values agree well with published data for normal ears. Studies of both normal and pathologic ears to predict the sound pressure level (SPL) existing under various source-load conditions are ongoing. Studies of the effects of manipulating ear canal air pressure on impedance quantities, on ear canal SPL, and on behavioral performance have been completed and are in progress.

Results—A previous implementation of the measurement system used a Hewlett-Packard 3582A spectrum analyzer while the current implementation uses a lower-cost instrument (Rapid Systems, Model R1200). During the past year, a study was completed on four normal subjects which demonstrated that impedance quantities obtained using either system were the same. In addition, using the current implementation, studies of cylindrical cavities, ranging in size up to 1.65 cm (in depth) and 19.8 cm (in length) demonstrated that measured quantities were in

good agreement with calculated quantities. A study of 15 normal subjects showed mean input impedance data (real, imaginary, and impedance magnitude) to be in good agreement with published data.

Finally, algorithms which used source and load impedance data to predict SPL developed in the ear canal have been implemented. A comparison of the SPL developed in the average ear (and in the Zwislocki coupler) with that predicted, showed good agreement. Studies of individual ears are being conducted.

Future Plans—Studies of the use of impedance quantities to improve the accuracy of prescriptive hearing aid fitting protocols are being planned. Radiographic studies of the human ear canal are being designed in order to facilitate the development of a clinically feasible, yet accurate, approach to quantifying the geometry of the ear canal.

Recent Publications Resulting from This Research

- A Comparison of Three HA-1 Couplers. Larson V, Cooper W, *Ear Hear* 10(5):330-334, 1989.
- Ear Canal SPL Relationships to Residual Volume and Venting. Cooper W et al., *ASHA* 31(10):117, 1989.
- Estimates of Aural Acoustic Impedance Quantities. Larson V et al., *ASHA* 31(10):123, 1989.
- Effect of Stiffening the Middle Ear on Word Recognition Ability. Cooper W, Larson V, Ball T, *ASHA* 32(10):117, 1990.
- Predicting SPLs in the Ear Canal by Acoustic Impedance Measurement. Larson VD, Cooper WA, Oliver JA, *ASHA* 32(10):145, 1990.
- Validation of an Aural Impedance Measurement System. Larson V et al., *Audiol Today* 2(2):32, 1990.
- Application of Acoustic Impedance Measures to Hearing Aid Fitting Strategies. Larson V, Egolf D, Cooper W, in *Proceedings of the Second Veterans Administration/Vanderbilt Conference on Amplification for the Hearing Impaired* (in press).

[420] Direct Measurement of Loudness Recruitment In Hearing-Impaired Veterans

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Sponsor: VA Rehabilitation Research and Development Service (Project #C296-2RA)

Purpose—This ongoing research program is primarily concerned with extending S.S. Steven's magnitude-scaling procedures to individuals with bilateral sensorineural impairments. The long-term goal is to determine the suitability of using cross-modality matching for the measurement of loudness in a routine clinical setting.

Methodology—Loudness measurements were obtained mainly by absolute magnitude estimation (AME), absolute magnitude production (AMP), and cross-modality matching (CMM). The measurements involved two sensory continua: perceived length and loudness. From these procedures, the slope of the loudness function was

obtained for individuals and groups. Slopes obtained directly from AME and AMP of loudness were compared to those predicted from CMM and AME of perceived length. In addition, both inter- and intrafrequency loudness matches were obtained by the conventional procedure of loudness balance. The stimuli were tone bursts that varied in frequency from 500 to 4000 Hz and lines of light displayed from 35 mm slides. All the measurements were obtained via earphone listening in a sound-proof booth.

Progress—During the past year, the project has focused on three research areas: 1) the effect of age on the growth of loudness in normal hearing; 2) the relation between magnitude scaling and loudness-balance results in impaired hearing; and, 3) the variability of the slope of the loudness function within and across groups in frequency regions of normal and impaired hearing.

To date, 129 people, most with noise-induced losses, have been tested at a frequency in the region of impaired hearing. From this group, 58 people were tested an additional two to seven times at frequencies in the regions of normal and impaired hearing. Loudness matches were performed by 18 people; the remaining loudness measurements were obtained by magnitude-scaling procedures. Data collection and analysis is continuing.

Preliminary Results—Mean slopes obtained for 33 older people (ages: 56-72 years) with normal hearing at 500 Hz are 0.59 determined from AME and AMP of loudness and 0.63 determined from CMM and AME of perceived length. These values are within one standard deviation of the slope of 0.56 obtained for a control population of 51 young people (ages: 16-24 years); they are also nearly the same as the slope of 0.6 established in an international standard.

A preliminary analysis of equal-sensation functions obtained by AME of loudness, AMP of loudness, CMM, and loudness matching indicates that the four procedures produce functions with similar overall shapes. However, on the average, the measured deviation of the slope of the CMM function from the slope obtained directly from AME and AMP of loudness is 0.2% and for loudness matching it is 17%. Unexpectedly, the measured deviation is smaller for the 10 people who performed interfrequency matches (9%) than for the 8 people who performed intrafrequency matches (27%).

In contrast to the known lack of relation between threshold measures and loudness comfort and discomfort levels, the ongoing analysis of the intra- and intersubject variability of the slope reveals that both the slopes and the standard deviations are positively correlated with the degree of hearing loss. Calculated for 129 different people with normal and impaired hearing, the product-moment correlation coefficient between the slope derived from CMM and measured hearing level is +0.81 ($p < 0.01$); for the same 19 people tested at three frequencies with different hearing levels the correlation coefficient is +0.88 ($p < 0.01$).

Future Plans/Implications—Future experiments will expand the study to a larger and more diverse population with respect to etiology. In addition, the long-term reliability of CMM will be evaluated, the questions raised by the results of loudness matching will be addressed, the growth of loudness across the audiometric frequency range in older adults with normal audiograms will be assessed, and the possible relation between the shape of the audiogram and the growth of loudness will be determined. Ultimately, CMM will be standardized for implementation into the clinical evaluation process.

Recent Publications Resulting From This Research

- Is a Power Function Description of Intensity-Jnd Data Compatible with the Loudness Function? Hellman W, Hellman R, *J Acoust Soc Am* 86:S98, 1989.
- Is Steven's Power Law Valid? Hellman R, *Behav Brain Sci* 12:276, 1989.
- Loudness of Two-Tone-Noise Complexes. Hellman R, Zwicker E, in *Proceedings of Inter-Noise 89*, Newport Beach, CA, 2:827-832, 1989.
- The Slope of the Loudness Function for Individuals and Groups with Normal and Impaired Hearing. Hellman R, Meiselman C, *J Acoust Soc Am* 85:S108, 1989.
- Intensity Discrimination as the Driving Force for Loudness. Application to Pure Tones in Quiet. Hellman W, Hellman R, *J Acoust Soc Am* 87:1255-1265, 1990.
- Loudness Measurements by Magnitude Scaling: Implications For Intensity Coding. Hellman R, in *Ration Scaling of Psychological Magnitude: In Honor of S.S. Stevens*, 215-227, G.A. Gescheider, S.J. Bolanowski (Eds.). Hillsdale, NJ: Lawrence Erlbaum Associates, Inc., 1990.
- Magnitude Scaling: A Meaningful Method for Measuring Loudness and Annoyance? Hellman R, Zwicker E, *Fechner Day 90*, International Society for Psychophysics, Wurzburg, Germany, 124-128, 1990.
- Loudness Relations for Individuals and Groups in Normal and Impaired Hearing. Hellman R, Meiselman C, *J Acoust Soc Am* (in press).

[421] Effect of Presence Versus Absence of Prolonged Amplification on Audition

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Sponsor: VA Rehabilitation Research and Development Service (Project #C578-RA)

Purpose—This longitudinal, prospective, large-sample investigation will examine the effects of a prolonged lack of auditory stimulation through failure to provide amplification on behavioral, neurophysiologic, and electro-acoustic measures of audition in adults with sensorineural hearing impairment. Subjects will be followed over a 3-year period. The results of this study will enhance understanding of communicative functioning with binaural versus monaural amplification and contribute to a theory of the effects of long-term lack of auditory stimulation on audition. The results will also contribute to a resolution of the problem of monaural versus binaural fitting. The specific research objectives of this proposed investigation are to: 1) periodically examine, over the 3-year period, the effects of lack of auditory stimulation (absence of amplification) on hearing sensitivity and speech perception and processing; 2) investigate whether a prolonged lack of auditory stimulation (absence of amplification) affects the absolute or interpeak latencies of the early, middle, and late auditory evoked potentials; 3) investigate whether a prolonged lack of auditory stimulation (absence of amplification) affects the threshold of the contralateral acoustic reflex; 4) investigate whether the effects of a prolonged lack of auditory stimulation (lack of amplification) are modified by subject variables at the onset of the study, including degree of hearing impairment, duration of hearing impairment, age, sex, unaided speech-recognition score, and length of interval between the onset of hearing impairment and date of hearing-aid fitting; 5) investigate whether the effects of prolonged lack of auditory stimulation in the unaided ear of the monaurally-aided persons are influenced by the ear (right versus left) aided; and, 6) determine whether the effects of prolonged lack of auditory stimulation in the

unaided ear of the monaurally-aided person can be halted, reversed, or offset by the introduction of binaural amplification.

Progress/Preliminary Results—Stimulus recording and calibration were set, patients were scheduled, and norms were established for Auditory Evoked Potentials for both males and females over and below 50 years of age. Sixty-five subjects, 35 with sensorineural hearing loss, 12 newly monaurally-fitted, and 23 binaurally-fitted subjects (experimental group), and 30 normal hearing subjects (control) were given the following tests: *Routine Audiologic Tests*. 1) pure-tone air-conduction thresholds; 2) pure-tone bone-conduction thresholds; 3) speech recognition threshold; 4) static-acoustic middle-ear admittance; 5) tympanometry; and, 6) contralateral acoustic-reflex threshold testing (visual monitoring of needle deflection with 5-dB increments).

Speech-Recognition Tests. 1) speech-recognition for CID W-22 monosyllabic PB words; 2) speech-recognition for nonsense syllables; and, 3) speech-recognition in noise for high predictability SPIN. Sentences (S/N ratio for the 50% recognition to be established using the adaptive procedure).

Electrophysiologic Testing. 1) brainstem auditory evoked potentials testing; 2) middle-latency auditory evoked potentials testing; and, 3) late-latency auditory evoked potentials testing was given only for selected subjects.

Future Plans—Our plan is to complete the first stage of this longitudinal study by March 15, 1991 by at least testing the minimum required subjects (163) as determined by statistical power.

[422] Perception of Reverberation by the Hearing Impaired

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Sponsor: VA Rehabilitation Research and Development Service (Project #C382-RA)

Purpose—Reverberant rooms act as acoustical filters with frequency responses typified by numerous ripples. Consequently, sounds occurring within these rooms have this rippled frequency response imposed upon their spectra, which are also marked by peaks and troughs. The perceptibility of these rather obvious acoustical characteristics of reverberant microstructure have received little attention to date, and their effects upon speech intelligibility have been similarly ignored. These issues pertaining to reverberant microstructure are addressed by this project.

Progress—Principal studies have addressed: 1) detection of spectral ripple in noise bursts involving the discrimination of 1/2-critical band wide peaks and troughs of up to 12 dB from flat spectra; 2) reverberation detection for noise bursts recorded in a room with a reverberation time approximating 0.4 s at locations differing in distance between source and microphone and their orientation with respect to the walls of the room; 3) smoothing reverberant spectra including digital filtering paradigms (ranging from 1/3- to 11 critical bands) addressing ripples occurring within and across critical bands; 4) development and standardization of a modified nonsense syllable test (MNST) involving the isolated presentation of 22 CVs and 16 VCs, with all consonant alternatives available as responses to each stimulus; and, 5) effects of reverberant microstructure differences on speech intelligibility, using recordings of the MNST made in a reverberant room as described above.

Results—Subjects with normal hearing were able to detect spectral peaks for which the difference limen approximate 3 dB; but spectral notches were not detectable with depths as large as 12 dB. Spectral smoothing using smoothing filters less than a critical band wide does not appear to be detectable. These findings are consistent with the concept that spectral ripple occurring between critical bands is more perceptible than spectral ripple that occurs within critical bands.

The performance-intensity functions resulting from the MNST were favorably comparable to the original nonsense syllable test (NST). Under nonreverberant conditions, most identification errors on the MNST involve fricatives and stops, and front place of articulation. (There was virtually flawless identification of semi-vowels, affricates, and nasals.) Confusions principally involved place-manner errors and tended to involve confusions between sounds sharing anterior place of articulation. Confusions involving voicing errors that are not possible on the NST were also revealed using the MNST. These results suggest that the MNST is well suited for the study of subtle differences in speech intelligibility due to differences in reverberant microstructure.

All reverberant conditions resulted in significantly poorer MNST scores than the nonreverberant condition. Recalling that the reverberant conditions differed with respect to location and arrangement in the same reverberant room, particularly important were the findings that there were significant differences in MNST scores among the reverberant conditions; and there were also some differences in confusion patterns between the various reverberant conditions. These results indicate that differences in reverberation microstructure result in differences in speech intelligibility that are measurable.

Future Plans/Implications—The results elaborate upon existing knowledge of reverberation perception and how speech understanding is affected by reverberation. Future plans include continuing investigation of the manner in which the reverberant microstructure affects the perception of reverberant speech quality and its intelligibility, as well as experiments to determine whether spectrum-smoothing paradigms result in perceptible changes in the quality and intelligibility of reverberant speech.

Recent Publications Resulting from This Research

Speech Recognition Performance on a Modified Nonsense Syllable Test (Abstract). Gelfand SA et al., *ASHA* 31(10):182, 1989.
Speech Audiometry: Modern Approaches (Abstract). Gelfand SA, *NYSSLHA Communicator* 19(5):22, 1990.

[423] A Prospective Randomized Cooperative Study of Advanced Cochlear Implants

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Sponsor: VA Rehabilitation Research and Development Service (Cooperative Study #304)

Purpose—This study was designed to compare the efficacy and safety of the 3M/Vienna® single-channel and three multichannel cochlear implant devices: Nucleus®, Symbion Ineraid®, and UCSF Storz devices.

Progress/Methodology—The study originally was to include a total of 120 patients accrued from 7 participating VA Centers (Ann Arbor, MI; Houston, TX; Iowa City, IA; Long Beach, CA; New York, NY; Seattle, WA; West Haven, CT), over a period of 3 years. An additional 2 years of patient follow-up to determine long-term efficacy is planned for all study patients. Delays in development of the UCSF device have necessitated a change in the study plan. Only three devices were to be studied in 90 patients. In November 1988, the 3M Company withdrew the 3M/Vienna single-channel device from the market. Twenty study patients had been implanted with the device. This decision has resulted in the limitation of treatment assignment to one of two multichannel devices. Only 80 patients in all will be accrued.

Introduction of a new speech processor design—Mini-Speech Processor (MSP)—by Cochlear Corporation has prompted further change in the study protocol. Patients implanted with the Nucleus® device will be provided the MSP following a minimum 2-year evaluation with the “older” WSP-3 equipment. Eligible patients include postlingual bilateral profoundly deaf individuals

who receive no benefit from appropriate amplification. Patients eligible for randomization must have no radiologic evidence of gross bony overgrowth of the cochlea. Intensive audiologic evaluations will be completed at 1, 3, 12, and 24 months after initial stimulation. Additional yearly assessments of the outcome measures of interest will be completed for each patient until the conclusion of the study.

Preliminary Results—Implantation has been completed with 82 patients randomized to the protocol. All patients received their assigned device with the exception of two patients who received a secondary (single-channel) device. Early data regarding benefit from implantation are encouraging. Quality of life measures suggest that patients are pleased with the early effects of cochlear implantation. The conduct of the study is progressing without difficulties.

Recent Publications Resulting from This Research

A Prospective Randomized Cooperative Study of Advanced Cochlear Implants (Abstract). Cohen NL, Second International Cochlear Implant Symposium, Iowa City, IA, 1990.

Use of Principal Components Analysis to Develop a Composite Score as a Primary Outcome Variable in a Clinical Trial. Henderson WG et al., *Controlled Clin Trials* 11:199-214, 1990.

[424] Early Detection of Hearing Loss from Ototoxic Agents by High-Frequency Auditory Evaluation: A Cooperative Study

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Sponsor: VA Rehabilitation Research and Development Service (Cooperative Study #C227-CSP)

Purpose—The primary goal of this initial study is to determine whether serial monitoring of high-frequency (≥ 8 kHz) sensitivity during treatment with aminoglycoside antibiotics or the chemotherapeutic agent cisplatin

will provide an earlier warning of impending hearing loss than with conventional frequency (≤ 8 kHz) hearing evaluation. Early warning will allow health care professionals to consider possible treatment alternatives, thus

reducing the potential for incurring communicatively impairing hearing loss. Secondary goals, such as the interactive effects of preexisting hearing loss and/or age, are designed to give more definitive information on the *process* of hearing loss caused by these ototoxic agents. Four VA Medical Center (VAMC) study sites are involved.

Progress—Computerized testing equipment was evaluated and modified in Portland, with the result that Macintosh-based audiometers and immittance meters were chosen for each site. All sites (Portland, OR; West Los Angeles, CA; Long Beach, CA; and Augusta, GA) are now on-line and collecting data. A data entry program developed at Portland VAMC allows all sites to enter personal and audiometric demographics into screen-viewed templates which are stored automatically in text file format. A data transfer program was developed at Portland VAMC to allow data from computers at each test site to be picked up via modem by the central computer in Portland. Data is then analyzed by the study biostatistician in Portland. A database program is currently being developed to allow automated data collection and analytical manipulation. To date, 157 subject candidates and 16 controls have been serially monitored during treatment with ototoxic or control agents.

Preliminary Results—From this early sample subject pool, in individuals with 4 or more days of treatment (3 or more hearing tests), $\cong 56\%$ of aminoglycoside antibiotic treatment subjects revealed significant negative hearing threshold change. In these subjects, $\cong 60\%$ of observed changes were seen to occur initially in the high frequencies (≥ 8 kHz), $\cong 38\%$ in the low (conventional) frequencies (≤ 8 kHz), and $\cong 2\%$ in both high and low frequencies. The percentage of observed change in aminoglycoside-treated subjects increased with increasing length

of treatment. Additionally, $\cong 85\%$ of cisplatin-treated subjects revealed significant hearing change. In these subjects, $\cong 45\%$ of the changes were seen to occur initially in the high frequencies, $\cong 14\%$ in the low frequencies, and $\cong 41\%$ in both high and low frequencies. Control subjects revealed unchanging responses during their treatment periods, demonstrating that ill, hospitalized patients can provide reliable data.

Future Plans/Implications—The current study protocol requires that 1- and 6-month evaluations be accomplished prior to classifying a subject as *Completed*. Many subjects have not yet reached this final stage, and experience-to-date has shown that many of these will not return for follow-up evaluations after their release from the hospital. Original criteria established for *Completed* subjects will be reassessed. A younger subject pool will be sought in an attempt to monitor the process of ototoxicity in more intact ears. Alternative treatment protocols for those revealing early warning signs should be explored. If the equipment and methodology developed here for high-frequency auditory evaluation proves to have potential for early detection of ototoxicity, the management of patients on aminoglycoside treatment protocols will be significantly enhanced by the incorporation of this methodology. As a next step, an intervention study should be conducted. The ultimate goal is the prevention of communicatively handicapping hearing loss in hospitalized patients who are at risk for such loss from routinely administered therapeutic agents with ototoxic potential.

Recent Publications Resulting from This Research

Reliability and Validity of High-Frequency (8-20 kHz) Thresholds Obtained on a Computer-Based Audiometer as Compared to a Documented Laboratory System. Fausti SA et al., *J Amer Acad Audiol* 1(3):162-170, 1990.

[425] Measurement and Prediction of Benefit from Amplification

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Sponsor: VA Rehabilitation Research and Development Service (Project #C344-2RA)

Purpose—The goals of this project are to determine the amount of benefit typically received from hearing aids in everyday life and to develop methods of quantifying and predicting hearing aid benefit for elderly listeners.

Progress—Investigations completed within the past year include: 1) a study of the effects of frequency response and visual cues on hearing aid benefit measured in daily-life settings using two objective procedures; 2) development and comparison of two questionnaires designed to

measure self-reported hearing aid benefit in daily life; 3) comparison of objectively measured and subjectively estimated speech intelligibility for elderly hearing-impaired and young normal-hearing listeners; 4) study of the accuracy of simulation of three everyday listening environments in an audiometric test room; and, 5) investigation of the efficacy of the Assessment of the Likelihood of Success with Amplification (ALSA), a questionnaire to allow audiologists to predict eventual hearing aid benefit, use, and/or satisfaction before an instrument is fitted.

Investigations in progress include: 1) a study of the evolution of hearing aid benefit in elderly persons who are acquiring their first hearing aid, and in experienced hearing aid users who are obtaining a new instrument; 2) assessment of the reliability of self-report hearing aid benefit; 3) evaluation of the relationship between self-assessed hearing aid benefit and adjustment to hearing loss; and, 4) comparison of three hearing aid follow-up management procedures in terms of their effect on short- and long-term hearing aid benefit.

Results—When hearing aid benefit was measured objectively using intelligibility improvement, benefit was greatest in quiet everyday environments and less in noisy and reverberant settings. Benefit was not very sensitive to moderate differences in frequency response nor was benefit changed when visual cues to speech were varied. Quantification of benefit using response time changes was largely consistent with the intelligibility data. However, response time changes did not reveal benefit differences across environments and did register benefit differences due to frequency response in a “cocktail party” type of setting.

The two self-report inventories for measuring hearing aid benefit produced quite different results. One suggested that benefit was greatest in quiet environments, whereas the other suggested that benefit was greatest in noisy environments.

As a group, elderly hearing-impaired listeners' subjective estimates of their own ability to understand speech were significantly lower than their objectively-measured intelligibility. This was not seen with young normal-hearing listeners.

Comparison of speech intelligibility in real and simulated listening environments revealed that inter-talker intelligibility differences and perception of certain phonetic features of speech could be fairly accurately preserved when quiet, noisy, and reverberant environments were simulated in an audiometric test room.

Evaluation of the ALSA indicated that it had no predictive validity and that there was little inter-audiologist agreement in completion of the questionnaire.

Recent Publications Resulting from This Research

- Comfortable Loudness Level: Stimulus Effects, Long-Term Reliability, and Predictability. Cox RM, J Speech Hear Res 32:816-828, 1989.
- Development of the Profile of Hearing Aid Performance (PHAP). Cox RM, Gilmore C, J Speech Hear Res 33:343-357, 1990.
- Evaluation of an In-Situ Output Probe Microphone Method for Hearing Aid Fitting Verification. Cox RM, Alexander GC, Ear Hear 11:31-39, 1990.
- Comparison of Objective and Subjective Measures of Speech Intelligibility in Elderly Hearing-Impaired Listeners. Cox RM, Alexander GC, Rivera I, J Speech Hear Res (in press).
- Hearing Aid Benefit in Everyday Environments. Cox RM, Alexander GC, Ear Hear (in press).

[426] Studies on Amplification Selection for the Hearing-Impaired Veteran

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Sponsor: VA Rehabilitation Research and Development Service (Project #C307-RA)

Purpose—The major purpose of this study is to evaluate the validity of three different hearing-aid selection procedures and the degree of fitting error associated with each procedure. Currently being evaluated are the revised National Acoustics Laboratory (NAL-R) method, the Memphis State University method, and the Prescription of Gain/Output method. The data collected will also

allow us to evaluate: 1) changes in user-satisfaction and measured performance over a 6-month to 1-year period following the hearing aid fitting; 2) the correspondence between laboratory measurements and the results of questionnaire data; 3) the correlation between real ear probe-microphone measurements and electroacoustic analyses in a 2 cc coupler; and, 4) factors which might

influence ultimate user-satisfaction with a hearing aid, such as certain audiologic patterns.

Methodology—Subjects are randomly placed into one of the three hearing aid selection protocols. Prior to the purchase of hearing aids, and at post-fitting intervals, each subject and a “significant other” are administered the Hearing Handicap Inventory for the Elderly (short form). The Hearing Aid Performance Inventory (HAPI) is also administered post-fitting.

Hearing aid fitting and evaluation follows the protocol pertinent to the particular selection method. A Fonix 6500 real-ear measurement system is used to verify the spectrum of the aided signal delivered to the eardrum. Once the hearing aids are adjusted to closely approximate the desired response, the Speech Perception in Noise (SPIN) test is used to indicate improvement in speech intelligibility. Behavioral measurements of functional gain and of loudness discomfort are also obtained.

Subjects return at approximately 1 month and 3 months after the hearing aid fitting for follow-up procedures. At these sessions, laboratory measurements and questionnaire data are reobtained. Some subjects will receive follow-up at 6 months and/or 1 year post-fitting.

Progress/Future Plans—In the past year, data have been collected on approximately 30 subjects at each site (for a total of 60), and selected data on prescription formula fitting error have been collected on an additional 60 subjects at the VA site. Entry into the computerized database and analysis of preliminary data has been accomplished, resulting in three research presentations. Data collection will be largely completed over the next few months. Two manuscripts are currently in preparation from the data.

Preliminary Results/Implications—Tentative results and conclusions of this study are as follows (questionnaire data has not yet been analyzed): 1) the degree of fitting error (difference between prescribed and obtained frequency response) is quite large under each of the formulas when analog in-the-ear (ITE) hearing aids are fit. The magnitude of fitting error does not differ substantially among the three formulas. There is a strong tendency toward overfitting of gain in the low- and mid-frequency region and definite underfitting in the high frequencies; 2) tolerance data, evaluated to indicate an acceptable return rate to the manufacturer, indicate that a fitting error of 15-17 dB would need to be tolerated at least one frequency between 250 and 4000 Hz for a 90% acceptance rate. Tolerances were similar for both real ear insertion gain and 2 cc coupler data; and, 3) the degree of fitting error found does not greatly exceed the degree of difference in prescribed gain among the three formulas. This result leads to the conclusion that, at least for analog ITEs, there is not a strong argument for using any one of these procedures over another.

Recent Publications Resulting from This Research

- The Vanderbilt/Veterans Administration Hearing Aid Selection Study: Interim Report. Sammeth C et al., presented at the Annual Convention of the American Speech-Language-Hearing Association, St. Louis, 1989.
- Clinical Experiences with Prescriptive Procedures for Hearing Aid Selection. Bratt G, Sammeth C, presented at the Second Veterans Administration/Vanderbilt Conference on Amplification for the Hearing Impaired, Nashville, 1990.
- Real Ear Measurements in Hearing Aids and FM Systems. Sammeth C et al., presented at the Annual Convention of the Tennessee Speech-Language-Hearing Association, Knoxville, 1990.
- Seminars in Hearing. C.A. Sammeth (Guest Ed.), February, 1990.
- Clinical Experiences with Prescriptive Procedures for Hearing Aid Selection. Bratt G, Sammeth C, in The Vanderbilt/Veterans Administration Hearing Aid Report II. G. Studebaker, F. Bess, L. Beck (Eds.). Parkton, MD: York Press, Inc. (in press).

[427] Development of a Digital Hearing Aid and Computer-Based Fitting System: Phase II

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Sponsor: VA Rehabilitation Research and Development Service (Project #C203-2DA)

Purpose—The purpose of this study is to develop a new hearing aid concept and a companion hearing assessment

and fitting procedure that will lead to improved performance of acoustic amplification for hearing-impaired people.

Methodology—Digital implementation provides greater fitting precision and flexibility with which to match the patient's hearing impairment. With digital implementation, the instrument can be connected to the fitting system, controlled, and monitored while the patient is wearing it. Therefore, the variability associated with earmold acoustics and head diffraction can be directly accounted for in the fitting of the aid. Digital implementation makes it possible to utilize adaptive filters for controlling gain and frequency response and for suppression of noise and feedback.

To provide for a systematic transition from research and development to evaluation to commercialization, a Steering Committee was established comprised, in part, of representatives from the VA Rehabilitation and Development Service and NASA's Office of Technology Transfer. This committee provides long-range planning and monitors day-by-day progress of project activities.

Results—During 1990, work focused on evaluation of the full-featured, bench-top digital hearing aid (designated BT2) with hearing-impaired subjects. Features include four channels of filtering with adaptive compression, feedback equalization, and noise reduction. Development of processing algorithms is complete and development of the custom circuitry for the analog/digital/analog converter, four-channel processor, and adaptive processor is nearly finished.

A fitting system utilizing 3M's MasterFit™ hardware was developed to support the BT2 model. It includes means for: 1) calibrating the hearing aid while the patient is wearing it; 2) adjusting the hearing aid parameters to conform to a specific prescription; and, 3) evaluating the resulting fit. Tests include tournament and paired comparison procedures, with which various settings and configurations of the hearing aid can be compared, and tests of speech intelligibility and speech reception threshold. This year over 500 experimental hours were conducted at the Central Institute for the Deaf with hearing-impaired subjects using the digital hearing aid (which was characterized at NIST—formerly the National Bureau of Standards).

The sound quality of the digitally-processed signals using log-based arithmetic was found to be excellent. Errors associated with fitting the aid to a target prescription were generally less than 2.4 dB rms and significantly smaller than the fitting error achieved with a commercially available, programmable analog reference aid. Typical NIST measurements, with the aid set to a nominally-flat gain function of 29 dB, were: 24 dB SPL input equivalent noise; 3, 3, and 1% harmonic distortion at standard test frequencies of 500, 800, and 1600 Hz, respectively; and, frequency range of about 100 to 6300 Hz.

Hearing-impaired subjects preferred the noise reduction feature for input signal levels from soft speech (55 dBA) to loud speech (75 dBA). Subject's word intelligibility scores improved for soft speech signals in the presence of machinery noise with noise reduction. The scores were similar to those obtained using the reference aid in quiet. Subjects also reported that, in general, the noise reduction feature improved sound pleasantness, most noticeably for high levels of speech-babble noise.

The feedback equalization feature made it possible for subjects to use a greater variety of amplification without the occurrence of feedback instability. This resulted in their selecting amplification characteristics of up to 10 dB greater in gain than they could achieve without equalization. Feedback equalization stabilized the acoustic coupling between hearing aid and telephone headset, making possible a more normal use of the telephone by hearing-aid wearers.

Future Plans/Implications—An important evaluation phase will begin during which a number of body-wearable digital hearing aids will be fabricated by the 3M Company and distributed to VA medical centers for field testing. The aids will be calibrated and fitted automatically with a PC-based fitting system similar to that described above. Several versions of the aid (programmable options) will be evaluated and the results will determine, in part, the final configuration of the aid that will be commercialized.

[428] Basic Mechanisms and Rehabilitative Strategies for Presbycusis: Part I

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Sponsor: VA Rehabilitation Research and Development Service (Project #C25I-2RA)

Purpose—Over the past funding period, we have determined the general auditory morphological and electrophysiological characteristics of the Coturnix quail throughout its entire actuarial life. This information has been used as a basis for studying the influence of environmental and systemic toxins on the auditory system during the aging process. In the process of determining interactive effects of aging and hearing loss due to noise exposure, we found that quail have the capacity to regenerate damaged and/or lost hair cells. This is the first evidence of such a restorative mechanism in vertebrates. The purpose of the current program is to address the issue of hair cell regeneration and re-innervation.

Progress/Preliminary Results—We have made a great deal of progress regarding the response of the senescent ear to acoustic trauma or ototoxic insult. We now know that hair cell loss is minimal as a function of aging in the quail but that ganglion cell loss is much greater. This lends support to the notion that ganglion cell loss seen in all senescent animals is a function of the aging process alone rather than species or disease-related degeneration. Further, we know that in the quail, hearing thresholds decline rather gradually with age. This corresponds well with the classical definition of human presbycusis as “minimal hearing loss with disproportionate discrimination loss” and lends support to the use of the quail as an animal model for the study of presbycusis. Thus, anatomical and physiological evidence suggest that some features of aging are similar to those found in many mammalian species. Other features, such as the regeneration of new hair cells following damage, are strikingly different and offer the possibility of new insights into the mechanisms of aging and the recovery of function in the auditory system.

It was during an experiment to determine the interaction of aging with acoustic trauma that we found a potential for hair cell regeneration after trauma. Previously, it was believed that no further production of hair cells could occur after terminal mitosis. However, we have now shown that mitotically quiescent cells within the cochlea of quail can be stimulated to division after acoustic trauma. In our most recent experiments, we show that this regenerative potential is maintained into the final years of life in the Coturnix quail. Quail at 100% of actuarial life (3 years) have minimal hair cell loss. Evidence from two normal birds shows the production of at least two new hair cells within the basilar papillae. We believe that this may be interpreted as evidence for some very low level of hair cell turnover and new hair cell production in the normal quail ear during aging. We do not believe that this represents a normal addition of cells throughout life, but rather a stimulated replacement of cells within the bird's normal complement of hair cells. Just what is the trigger for new hair cell production during aging? Is cell death and extrusion necessary? How does the status of the whole organism (i.e., hormonal status) influence the triggering of new hair cell formation? Future studies will be designed to address these issues.

Implications—As a consequence of these studies, we have found the first evidence for the stimulation of new hair cell production in mature vertebrates. Future experiments should provide insight into a heretofore unknown potential for recovery of hearing after trauma or during old age. The study of hair cell regeneration in nonmammalian species may provide rational approaches toward stimulation of hair cell regeneration in mammals.

[428a] Basic Mechanisms and Rehabilitative Strategies for Presbycusis: Part II

Purpose—Concurrent with the anatomical and electrophysiological studies in birds, we are exploring the possibility of an altered preference for frequency response and/or gain characteristics of amplification in the elderly

human hearing-impaired population. Specific questions are: 1) Is there an altered preference for frequency and/or gain characteristics of amplification devices in the elderly? 2) Do any particular formula approaches approximate

these characteristics better than others? and, 3) Does the use of noise reduction influence these desired frequency/gain characteristics?

Progress/Preliminary Results—The first question was approached by measuring the real ear insertion gain/frequency response of currently worn hearing aids in satisfied users under the age of 60 and over the age of 75. These results have been published. We found no difference in preference for frequency/gain characteristics as a function of age. Further, when the four formulae (Berger, POGO, NAL revised, and Libby one-third gain) were applied, most were fairly accurate in their estimation of use gain up to 2,000 Hz. Above 2,000 Hz, all formulae over-predicted gain currently in use. The revised NAL formula and the Libby one-third gain rule provided the best estimate of use gain.

The finding of a reduced preference for high frequency gain in older veterans led us to design a second experiment. Using the Phoenix hearing aid, we were able to simulate various frequency/gain response slopes either in a matrix selection procedure or in an adaptive comparison task. Technical difficulties with the calibration of the system delayed rapid progress with this experiment. However, results are now sufficiently robust to state that, when available (that is, not limited by the "plumbing" of the system, e.g., earmolds, vents, etc.), the older veteran would prefer the high frequency gain prescribed by such formulae as the revised NAL.

We are currently using the adaptive comparison task to determine the objective and subjective effects of a noise reduction paradigm on speech intelligibility and hearing aid user preference. Approximately 12 veterans have completed the objective (SRT on the SPIN test under linear and nonlinear, noise reduction conditions) and subjective portions of the experiment. In the subjective portion, the veteran is given a digitally programmed hearing aid with two unmarked selection modes (linear and nonlinear). He is then asked to wear this aid for one week, keeping an extensive diary of the selection mode

(green or red button) and environment. Results to date are ambiguous. Objectively, there is no significant difference in the SRT obtained between linear and nonlinear modes. There are some rather interesting individual differences; however, the general trend is of no real advantage for a nonlinear versus linear system. All subjects, of course, performed better in the aided condition. Subjectively, we have observed no substantial advantage for either system. Again, individually there are interesting findings. For example, one veteran chose the nonlinear setting for all situations and was so impressed with it that he wanted to buy it. On his objective tests no real advantage was shown.

Future Plans/Implications—We plan to continue this study, with some alterations in design (taking other nonlinear noise reduction modes into account) in the future.

These results suggest that the current prescriptive formulae are generally adequate to predict use gain in most older veteran hearing aid users. The formulae which seemed closest to predicting use gain were revised NAL and one-third gain rule. Further, nonlinear noise reduction strategies seem beneficial to some veterans but not others. Future studies will continue to explore the area of noise reduction and objective/subjective benefit.

Recent Publications Resulting from This Research

- Continued Ganglion Cell Loss After Hair Cell Regeneration. Ryals BM, Ten Eyck B, Westbrook EW, *Hear Res* 43:81-90, 1989.
- Regeneration of Hair Cells in the Chick Basilar Papilla Following Gentamicin Toxicity (Abstract). Lippe WR, Ryals BM, Westbrook EW, *Assn Res Otol* 12:96, 1989.
- Differences in Hearing Aid Gain as a Function of Age. Ryals BM, Auther LL, *Hear Instrum*, April, 1990.
- Hair Cell Regeneration After Acoustic Trauma in Senescent Coturnix Quail (Abstract). Ryals BM, Westbrook EW, *Assn Res Otol* 13:365, 1990.
- Hair Cell Regeneration in Senescent Quail. Ryals BM, Westbrook EW, *Hear Res* (in press).
- Issues in Neural Plasticity as Related to Cochlear Implants in Children. Ryals BM, *Am J Otol* (in press).

[429] Sign Language Telephone

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The sign language telephone is a communication device for the hearing impaired. It will allow real-time transmission of visual images via phone lines, contrasting the current TDD (Terminal Device for the Deaf) technology which transmits keyboard input.

Progress—The two main problems to be solved in this project are: 1) efficient extraction of the outline image; and, 2) compression of the resulting data for transmission on limited telephone bandwidth. During the past year, the goal of extracting the image in 0.10 seconds or better has been achieved. Software to animate the outline images was also developed, leading to the development of a real-time, operational demonstration unit. This demonstration unit extracts the outlines of a subject seated in front of a video camera and animates them on a monitor connected to a PC at a rate of approximately 10 frames per second.

Methodology—sign language telephone consists of two identical stations which communicate via 19.2 K baud modems across phone lines. Required hardware includes a video camera and monitor (512 × 512 resolution), and a PC (minimum speed 20 mHz) with several parallel-processing boards (transputers) for real-time image processing at each station. The system is set up with the video camera and monitor located approximately 5 feet from, and focused on, an armless stool and a backdrop of solid color, nonreflective cloth whose dimensions are sufficient to cover the entire monitor image. The user

dials the receiving station, seats himself in front of the camera, and “speaks,” using sign language. The PC extracts and transmits an outline of the image of the user 10 times per second.

Preliminary Results—The edge-extraction algorithm is complete and operating at our goal of 0.10 seconds (or 10 video frames per second). The problem of representing the edge-extracted images on a monitor has also been solved. Ongoing tests at Gallaudet University will determine if these images are intelligible. Based on the edge-extraction algorithm, a demonstration station has been developed.

Future Plans—Work for this year will focus on compressing the edge-extracted images for transmission over the telephone lines at a rate of 19.2 K baud. Once complete, we will develop a demonstration system that will allow for two-way signed conversation over the telephone. This system will then be used for intelligibility studies.

Recent Publications Resulting from This Research

The Development of a Visual Telephone for the Deaf: Using Transputers of Real-Time Image Processing, Transputer Research and Applications 3. Galuska S, in Proceedings of the Third Conference of the North American Transputer Users Group, IOS Press, 1990.

A Real-Time Visual Telephone for the Deaf. Galuska S, Foulds R, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 267-268, 1990.

[430] Local Area Network Image Transmission

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Sponsor: *National Institute on Disability and Rehabilitation Research; Nemours Foundation*

Purpose—The local area network image transmission system is a communication device. The intended use of this system is to enable deaf individuals to lead a video conversation through a local area network. This facility would be very useful in an office environment.

Progress—The goal of this project is to show that it is possible to implement an image transmission system that will perform real-time visual communication using relatively affordable equipment. Indeed, we managed to implement the visual communication system using

general-purpose hardware and software tools, especially a very cheap camera and image-grabbing system.

Methodology—The images are obtained by using a small, inexpensive Electrim's EDC-1000 Computer Camera, sent across the network using FTP Software's PC/TCP Network Software and Western Digital WD8003 interface at one end of the connection; the images are received and displayed on the screen at the other end of the connection. The image resolution is 64 by 64, which allows one frame to be placed into the TCP packet. This allows maximum performance over the Ethernet Computer Network we are using.

Results—The animation rate that we achieve is 9 frames/second and is limited almost exclusively by the low-speed camera, which can grab only 9 frames/second. Again, the network delay is minimized and appears to be negligible. This animation rate is sufficiently intelligible.

Future Plans—The future perspective of this project would be a two-way visual communication system. This will enable two sign language speakers to communicate simultaneously with each other through a local area network, just as hearing people use a telephone today.

[431] A Study of Successful Deaf High School Students

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This study is an investigation into social, linguistic, cognitive, and academic success among high school students with severe or profound hearing loss. The project is constructed as an in-depth investigation of a sample of 23 students, nominated by their teachers from schools in different parts of the country.

Progress/Methodology—Two teams of two researchers, one deaf and one hearing, visited each school site and interviewed the students and one or both parents or guardians separately, and videotaped the student and parent(s) conversing together. Parent interviews included the Vineland Scale of Social Adjustment, and questions about the family history, especially as it related to the

student. Interviews with the students included an examination of their levels of social cognition, and questions about their relationships, schooling, upbringing, why they thought they were successful, and their future plans. Nominating teachers also completed a questionnaire, students provided an on-the-spot writing sample, and information on standardized test scores, and audiological and psychological examinations was obtained from school records.

Results—The results will be reported as a series of case studies, as well as a review of common themes. Separate subanalyses will be conducted on the writing samples, the parent-student interactions, and the social cognition data.

[432] A Social Cognition Program for Deaf Adolescents and Adults

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this long-term project is to develop, implement, and evaluate a social-cognitive group program to raise the levels of social functioning of deaf adolescents and adults. The program aims to compensate for gaps and losses in the developmental social experience of those deaf individuals who are low-functioning by implementing a group program which

provides opportunities for mediated learning in the social domain.

Progress/Methodology—Group activities are selected and/or developed which structure opportunities to think (understand and reason) about people, about relationships, and about social events and issues in a guided way.

We hypothesize that if a program of mediated intervention can raise levels of social cognition (perspective taking, person conceptualization, communication, and social causal reasoning and problem-solving), then improved social and socioemotional functioning will follow. The project design includes phases for development, piloting, refinement, and evaluation of the program with groups of deaf adolescents enrolled in high school, and with groups of deaf adults not enrolled in any regular program. The evaluation phase includes the development of a rating measure of social functioning for use by teachers and counselors, and an experimental design

comparing matched treatment and control groups for changes related to participation in the social-cognitive group program.

Recent Publications Resulting from This Research

A Program to Enhance the Social Cognition of Deaf Adolescents. Lou MWP, Charlson ES, in *Cognition, Education and Deafness*, D. Martin (Ed.). Washington, DC: Gallaudet University Press (in press).

A Social-Cognitive Group Treatment Program. Lou MWP, Charlson ES, in *At the Crossroads: A Celebration of Diversity*, D. Watson (Ed.). Little Rock, AR: ADARA (in press).

[433] Effects of Interpreter Training on Rorschach Scores

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This project attempts to assess the effects of training sign language interpreters in Rorschach testing on the Rorschach scores of deaf clients.

Progress/Methodology—Two groups of sign language interpreters, one trained on the Rorschach, one untrained, will interpret a set of videotaped signed Rorschach responses by deaf clients working with a signing psychologist. These interpretations will be transcribed and subsequently scored from the written protocols by psychologists who have no knowledge of the participants or the object of the study.

Results/Implications—By examining the differences in results from interpreted versus uninterpreted responses, and by looking at the effects of specific interpreter training, we hope to provide information that will enable clinicians working with deaf clients to avoid misdiagnoses and misprognoses that might otherwise occur, and hence to provide a better service for individuals with deafness. Our plan will be to create a training program for interpreters who work in clinical settings, and should training prove to be a significant factor, establish workshop components for mental health professionals in the use of Rorschach with deaf clients, based on our findings.

[434] Linguistic Indicators of Thought Disorder Among Deaf Mental Patients

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This study is concerned with whether and how linguistic indicators of disordered thinking are represented in the sign language of deaf psychotics, and whether other linguistic phenomena, hitherto unrecognized, are evident in the language of deaf psychotics.

Methodology—The first objective of this project is to examine language samples from a number of deaf persons

who have been diagnosed as psychotic, to see if any of the specifically linguistic indicators of psychosis as described in the *Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R)* are present in the corpus, and if so, what particular forms they take. Secondly, there will be a search for other linguistic irregularities that might characterize the signing of psychotic deaf patients, but which do not fall under the categories listed in *DSM-III-R*.

Results/Implications—We hope to convert the information gleaned from this research into training programs for clini-

cians and interpreters, so that services to deaf patients might be improved, and the number of misdiagnoses reduced.

[435] Identification of Organic Impairment Through Neuropsychological Assessment

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The project is a methodological study to develop an approach to the neuropsychological assessment of deaf psychiatric patients, when the task is to discern organicity from functional disorders. It seeks to identify the instruments and procedures that are most powerful in differential diagnosis among the deaf population. It also seeks to identify the instruments most sensitive to subgroups within this population (e.g., groups defined by age range or cognitive abilities).

Results/Implications—The benefits of this research are expected to be the following: 1) professionals who test

deaf psychiatric patients will be able to employ (with an enhanced sense of diagnostic confidence) the specific instruments and techniques identified in this study; 2) instruments that are particularly unreliable can be identified and counter-recommended; 3) research findings will provide a preliminary test-performance database and normative values for deaf psychiatric patients; and, 4) with respect to these particular research participants, each will have a set of assessment data gathered which can be used by their respective professionals as part of their treatment.

[436] Ethnography and Evaluation of DeafCAN: A Program for Minority Deaf College Students

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The DeafCAN program is a postsecondary education intervention serving population of inner-city, minority deaf students who often do not demonstrate educational potential on placement exams. The purpose of this project is: 1) to describe the program in comprehensive detail; 2) evaluate its effects on the social, psychological, and academic development of its students; and, 3) from that description and evaluation, to develop a model program for dissemination.

Methodology/Implications—The study is designed around an ethnographic investigation of the program, using long-term observation of all aspects of the program

in action, interviews with program participants, employment of staff as participants in the research, collection of materials used in the classroom, student writings, etc., and the recording of staff comments in response to their viewing of videotapes of their program in operation. These data are used to write an extensive description, or ethnography, of the program. The ethnography, together with data on student goals, achievement, attrition, and teacher reports, will be used to formulate an evaluation of the program, which will address both formal goals as articulated by the program staff, and informal goals and achievements (or lack of them) as divined from the observational data.

[437] Peer Counseling Programs for Deaf Clients

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this study was to describe programs that offer peer counseling for deaf clients.

Progress/Methodology—Eight peer counseling programs for the Deaf in Northern and Southern California were investigated. Personal interviews were conducted with 12 individuals, either peer counselors or program directors, by a signing, licensed clinical social worker. Interviews were videotaped and lasted from 60 to 90 minutes. Questions were directed toward eliciting as much information as possible, including the kinds of problems that were addressed, who used the service, referral sources, the backgrounds of the counselors, philosophy, details of counselors' activities, problems, ideas for improvement, etc. The interviews were then examined with two questions in mind: How did these services compare with other programs for the deaf? How did these programs compare with peer counseling programs in other settings?

Results—It was concluded that these programs perform a vital function in the local deaf communities primarily through advocacy work, by encouraging self-sufficiency, and providing role models which support the notion that deaf people can function successfully and independently. There were several ways in which these programs differed from other peer counseling programs: one-quarter of the counselors were not themselves from the peer group they served (i.e., they were hearing); most received no training in peer counseling; and they did not focus primarily on problems arising from the shared experiences of counselor and client.

Recent Publications Resulting from This Research

Peer Counseling Programs for Hearing-Impaired Clients.

Strong M, Day-Drummer C, *J Am Deaf Rehabil Assoc* 23(4) (in press).

[438] Therapeutic Preparation of Deaf Clients

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose/Methodology—This project provides deaf clients presenting for psychotherapy with an educational videotape (using the language of the client's choice), that provides information about psychotherapy. The specific objectives of the project are to: 1) assess the attitudes and knowledge about psychotherapy possessed by deaf clients in a public community mental health setting; 2) develop

videotape materials providing education and socialization for deaf psychotherapy candidates; 3) demonstrate the effectiveness of the videotape materials in providing educational content; 4) evaluate the potential benefit of preparation for psychotherapy for deaf clients presenting for psychotherapeutic intervention; and, 5) disseminate results and materials from this study.

[439] Signaling Systems/Alternative Technologies for Deaf and Severely Hard of Hearing People

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Sponsor: National Institute on Disability Rehabilitation and Research

Purpose—The Lexington Rehabilitation Engineering Center (REC) has been charged by the National Institute on Disability Rehabilitation and Research with working on the development of better signaling systems that use senses other than hearing for deaf and hearing impaired people. Gallaudet's subcontract involves production of state-of-the-art reports, investigations of trends in this area of technology, evaluations of prototypes, and other work related to visual communication by deaf and hard of hearing people.

Progress—At Gallaudet, the first year of the project was directed at acquiring signaling systems in use by deaf and hard of hearing people. A resulting monograph, published through the Gallaudet Research Institute, gives an in-depth description of signaling devices on the market. A second report covering all visual technologies used by deaf and hard of hearing people has been written and edited and is currently in production. This report covers telecommunications, broadcast media, face-to-face communication, and environmental awareness.

The second year of the project involved investigation of home automation systems and tracking of standards in home automation. General-market home automation products are applicable to the needs of deaf people but, as is often the case, have some drawbacks as well. A report on home control has been written, with emphasis on the X-10 standard and an analysis of its implications for home control.

The third year of the project shifted focus from signaling systems to certain aspects of telecommunications. An ongoing debate in the deaf community has centered around the separateness of the deaf TDD network, which operates in baudot code and is thus incompatible with computers for communication. A number of TDD products do contain ASCII, but ASCII is rarely used by deaf people for telephone conversation. Investigators are therefore evaluating the compatibility of ASCII-based TDD products (external translation modems, internal translation boards, and ASCII modules in TDDs) with: 1) each other; 2) Hayes modem at 300 baud; and, 3) the VAX system at Gallaudet.

Results—It became clear early in the investigation that some of the problems with compatibility of the devices could be solved if manufacturers would agree to standard default parameter settings for these products. To that end, a meeting of manufacturers was convened at the National Association of the Deaf convention in Indianapolis. A second meeting was scheduled for January 1991.

Future Plans—Gallaudet will also evaluate prototypes developed by the REC as they become available for evaluation; participate in the dissemination activities of the REC; and work toward public-domain software for Hayes modems, designed for the application of deaf-hearing conversation on standard computers and modems.

[440] Innovative Technology for Deaf and Hard of Hearing People/Integrated Computer Workstation for Deaf Individuals

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This is a two-part demonstration project on commercially available visual technology that could be used by deaf and/or hard of hearing people but is not yet in use.

University of Delaware: Integrated Workstation. A barrier to the successful application of new technology for deaf individuals is often the result of the independent

nature of the products. While the features of the different devices are desirable, there are practical difficulties in employing multiple technologies at the same time. Since much of the new hardware and software is based on commercial microcomputers, it is feasible to consider bringing a number of these concepts together in a unified system that offers the combined advantages of all of the constituent parts.

The project will promote the use of microcomputer hardware and software in powerful, integrated workstations. The goals of the project are to: 1) identify the modes of telecommunication that can be used effectively by deaf individuals; 2) demonstrate that a variety of commercial and near-commercial prototypes can be integrated into a working system; and, 3) evaluate the system for user acceptance and technical performance.

Specific areas of interest are: telephone monitoring, touch-tone decoding and voice response, visual intercom for local area network, and office productivity.

Gallaudet: Innovative Technologies. This is a demonstration project on commercially available visual technology that could be used by deaf and/or hard of hearing people, but that is not yet in use. Most of the technological applications to be demonstrated meet the following criteria:

- deaf and hard of hearing people are not making use of the technology
- potential for successful application is high
- little or no training or clinical intervention is needed
- technology is likely to remain on the market for several years
- technology is affordable to intended purchaser (individual, school, etc.).

The procedures have been as follows: 1) identify candidate technological applications; 2) canvass market for products and acquire products; 3) test out application in-house; 4) develop training procedures and materials, if needed; 5) develop procedure for data collection (observation, user logs, interviews, questionnaires, etc.); 6) select sites for demonstration; 7) place technology in site; 8) train users, if necessary; 9) collect data/feedback from users; 10) publish information on technology/application and users' reactions; 11) produce videotape on technology; and, 12) disseminate videotapes.

Methodology—The primary dissemination mechanism for the project will be videotape, which will be produced in-house. Articles are also being placed in user publications. Applications being explored include the following:

- computer projection and standard keyboard for computer-assisted notetaking during meetings and lectures
- security cameras and monitors for a video intercom
- new captioning software that permits people to caption their own videos (demonstrated with teachers)
- computer-based TDD products
- fax with and without voice feature
- standard camcorders and other moderately priced products for in-house production of video
- evaluation of speech recognition system for computer-assisted notetaking
- reverse-polling devices for fax, for approximating audiotex services through fax.

[441] Feature Extraction Methods for a Video Telephone for Deaf and Hard-of-Hearing People

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Deaf and hard-of-hearing people are very interested in the prospect of having video combined with telephony for purposes of conversation. Among many deaf people, the goal is to be able to sign on the phone; this would allow a natural communication counterpart to voice communication enjoyed by hearing telephone users. The purpose of this project is to develop image compression techniques to allow the trans-

mission of intelligible sign language over residential telephone lines.

Methodology—Because the bandwidth of ordinary residential telephone lines is so narrow, transmitting actual video images of a person communicating in sign language in real-time is impossible. The amount of video data needs to be compressed by an approximate 1000:1

ratio. Therefore, techniques must be developed not only to perform this data compression, but also to do it quickly enough for conversation to take place.

The first step in compressing the vast amount of data into a video image is to perform an edge-detection; that is, to find the outline of the signer. This identifies the outline of the hands, fingers, and other important features such as facial expressions (which convey part of the grammar of American Sign Language). Once the edge-detection is performed, the result is an image of individual pixels (dots). The next step is to attempt to draw curves (contours) through a continuous set of pixels; therefore, a set of individual pixels could be determined by merely transmitting the end-points of the curve, and possibly one or two intermediate points. The final data compression method used avoids processing every video frame; instead, it skips frames and reconstructs intermediate frames on the receiving end. Video is normally

captured at a rate of 30 frames per second; we are attempting to be able to process 7.5 frames per second, or processing every fourth frame. The resulting images are then animated on a standard computer monitor. What is seen by the receiver are the edge-detected, contoured images of the original signer in animation.

Progress—Intelligibility trials were conducted at Gallaudet University, involving 120 deaf adults as human subjects. Data analysis is under way. The primary goal of the analysis is to determine the lowest frame rate at which signing is intelligible, using the University of Delaware's algorithm. Effects of the signer effects, lip movement, and speed of fingerspelling are also being examined.

Future Plans—A real-time system is now being built, and evaluation of the system for conversation will be done at Gallaudet in 1991.

[442] Adaptive Capabilities of Postural Stabilizing Reflexes

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Sponsor: National Institute on Deafness and Other Communication Disorders, National Institutes of Health

Purpose—This research seeks to understand the adaptive capabilities of the postural stabilizing reflexes in patients with imbalance in order to guide the direction of rehabilitative interventions with vestibular-deficient patients.

Progress/Methodology—The postural stability of a sample of patients with bilateral vestibular loss due to ototoxicity has been studied to date. By quantifying body sway while systematically varying the visual surround

and support surface, it has been established that this patient group relies more on visual cues than on proprioceptive cues to maintain postural stability. In addition, bilaterally deficient vestibular patients do not always adopt "hip strategies" to maintain balance, as proposed by others. The effects of moving visual stimulation and of inducing vestibulo-ocular reflex adaptation with magnifying spectacles on postural sway is now being studied in patients with balance and vestibular disorders.

[443] Cochlear Implant and Tactile Aid Studies with the Deaf

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Sponsor: National Institute on Deafness and Other Communication Disorders, National Institutes of Health

Purpose—Deaf children are taught to perceive and produce speech by means of several devices: hearing aids, cochlear implants, vibrotactile devices, and speech-reading unassisted by amplification or cross-sensory devices. This project is focused on assessing the efficacy of speech perception and production training of deaf

children who have been fitted with single- or multi-channel cochlear implants, or who receive input via vibrotactile devices.

Preliminary Results—We have found that all children make significant gains in perception and production skills;

however, those with multi-channel cochlear implants show superior performance in all dimensions, where the performance with vibrotactile devices and single-channel cochlear implants is approximately the same. Adults who acquire hearing impairment most often use a combination of hearing aids and speechreading to achieve auditory reception.

Dr. Harry Levitt and his colleagues at the City University of New York have developed a highly sophisticated and effective video training program to teach speechreading skills. This program is unique in that it can be used by the patient alone in practice without the constant and direct intervention of a therapist.

B. Speech Impairment

[444] Computer-Assisted Speech Evaluation Expert System

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Sponsor: VA Rehabilitation Research and Development Service (Project #C468-RA)

Purpose—This research program is devoted to developing and testing specific computer and instrumental procedures designed to measure aspects of speech and speech-related function in subjects with disordered speech. Software is being developed to extract and analyze acoustic, aerodynamic, and physiologic speech data during connected speech and specific diagnostic maneuvers. Expert systems are being developed to provide interpretation of obtained speech deviance profiles and provide advice regarding optimum sequencing of diagnostic tasks.

Progress/Future Plans—The initial development period has just ended. This work focused on development and validation of acquisition and quantitative analysis procedures that result in objective measures of speech function. Pilot data have been collected on more than 230

normal and disordered subjects for various protocols. The next phase will focus on development of expert system functions to assist the professional in diagnostic evaluation of speech disorders. Specifically, the software will: 1) recommend order of protocol administration and, when necessary, recommend additional procedures not available among the protocols; 2) describe subject performance in relation to normative data; 3) provide hypotheses relating speech and physiological performance; and, 4) provide descriptive conclusions regarding a subject's speech disorder. Concurrent work will provide formal descriptive measures for clinical groups of speech-disordered subjects and for normal subjects. These data will be studied in relation to human perceptual judgment and expert panel opinions to evaluate and refine the expert system components.

[445] Hierarchical Computerized Language Treatment for Aphasic Adults

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Sponsor: VA Rehabilitation Research and Development Service (Project #C400-RA)

Purpose—Recent reports imply that microcomputers may be effective for providing language treatment to aphasic adults. The current project is based on earlier work by the investigators, and expands the use of complex algorithms and hierarchically arranged language tasks to deliver reading and writing treatment appropriate for each patient's

level of severity. The purpose of the study is to develop hierarchically arranged reading and writing treatment software and to test its effectiveness by comparing improvement in patients who receive computerized language treatment with that of patients who receive computer stimulation ("non-language" activities), or no treatment.

Progress—Approximately 100 subjects have been entered into the study and we continue to recruit additional subjects. Subjects have been assigned to all four groups: computer reading treatment, computer writing treatment, computer stimulation, and no treatment. Both the reading and writing treatment programs run with minimal problems.

Methodology—This study employs a group design and uses two treatment groups and two control groups. Subjects are assigned randomly to the computer reading treatment group, the computer stimulation group, or the no treatment group. After participating in the study for 6 months, subjects are assigned to the computer writing treatment group. Subjects in computer groups receive 72 hours of computer use. Change for each group is compared at 3 and 6 months on the Porch Index of Communicative Ability (PICA), the Western Aphasia Battery, the Raven Colored Progressive Matrices, and two nonstandard measures of reading and writing.

Preliminary Results—Fifty subjects participated for 6 months. All 15 subjects in the computer reading treatment group learned to use the program successfully within three sessions and completed an average of 140 tasks (range 88 to 232). The computer reading treatment group demonstrated statistically significant changes ($p < 0.01$) in PICA Overall, Reading, and Verbal modalities over 6 months, and showed other changes for the first 3 and last 3 months ($p < 0.05$). In contrast, the Computer Stimulation group demonstrated only one statistically significant change ($p < 0.05$), the PICA Overall value, for the first 3 months. The No Treatment group did not show

any statistically significant changes. When an analysis of variance (ANOVA) was performed, the Computer Reading Treatment group differed from the other two groups ($p < 0.05$) for the PICA Overall and Verbal modality values at 6 months, from the No Treatment group for the first 3 months, and from the Stimulation group for the second 3 months. At no time were statistically significant differences found between the Computer Stimulation group and the No Treatment group.

Future Plans/Implications—Additional subjects continue to be recruited. Results at this time imply that: 1) computer reading treatment can be administered with minimal assistance from a clinician; 2) improvement on the computer reading treatment tasks generalizes to improvement on non-computer language performance; 3) improvement results from the specific language content of the software and not simply from the stimulation provided by the computer; and, 4) chronic aphasic patients can improve performance through computer treatment.

Recent Publications Resulting from This Research

- Treatment Software for Aphasic Adults. Katz RC, in *Integrating Theory and Practice in Clinical Neuropsychology*, 317-335, E. Perecman (Ed.). Hillsdale, NJ: Lawrence Erlbaum Associates, Inc., 1989.
- A Comparison of Computerized Reading Treatment, Computer Stimulation, and No Treatment for Aphasia. Katz RC et al., in *Proceedings of the 1989 Conference on Clinical Aphasiology* (in press).
- Computerized Hierarchical Reading Treatment in Aphasia. Katz RC, Wertz RT, *Aphasiology* (in press).
- Intelligent Computer Treatment or Artificial Aphasia Therapy? Katz RC, *Aphasiology* (in press).

[446] Cortical Auditory-Evoked Potentials and Behavioral Measures of Aphasia

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Sponsor: VA Rehabilitation Research and Development Service (Project #C493-RA)

Purpose—The purpose of the project is to examine hemispheric processing of language by 20 stable and 15 recovering aphasic patients by using late auditory-evoked potentials as direct electrophysiological measurement of hemispheric involvement.

Methodology—Subjects undergo a behavioral testing battery including the Porch Index of Communicative

Abilities (Porch, 1967); the Boston Diagnostic Aphasia Examination Severity Index (Goodglass and Kaplan, 1973); a handedness questionnaire; and a bilateral hearing screening at 500, 1k, and 2k Hz. Evoked potential testing is made up of a right hemisphere task (music), a left hemisphere task (language), and a nondifferentiating task (noise). While the subject is actively involved in processing the information in the task, evoked potentials

to irrelevant auditory probe tones are used as the measure of hemispheric involvement in the task. Measurements of electrical activity are bipolar from central midline sites as compared to temporal sites on each side of the scalp. Stable patients will receive this paradigm on two separate occasions; recovering patients will be tested longitudinally at monthly intervals.

Progress—To date, eight stable aphasic patients, and five normal controls have been tested with the entire

paradigm. Three recovering aphasic patients are in the process of being tested at monthly intervals. Both normal control and aphasic subjects are continually being identified and scheduled for inclusion in the investigation.

Recent Publications Resulting from This Research

Cortical Evoked Potential Instrumentation with Aphasic Patients. Prescott TE, Selinger M, presented at the American Speech and Hearing Association Convention, Seattle, 1990.

[447] Development of Microcomputer and Clinician Treatment Procedures for Aphasia

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Sponsor: VA Rehabilitation Research and Development Service (Project #C343-2RA)

Purpose—The use of microcomputers in the rehabilitation of brain-damaged patients continues to win popularity in some clinical settings. Cost-effectiveness, operational efficiency, and increased treatment time allocations without additional human resources are the features that bolster their acceptance and application. Yet databased research in speech/language pathology concerning treatment efficacy remains sparse. The field presently lacks convincing data as to the efficacy of using microcomputers for the rehabilitation of aphasic adults. The purpose of the present study is to answer the following questions: 1) Are clinician-assisted microcomputer treatment programs as efficacious in treating marked aphasic individuals as they are compared to treating moderate to mild aphasic individuals? 2) Is linguistic cueing hierarchy different for various types and levels of aphasic persons? and, 3) Can streamlining a recueing verb-treatment package, by eliminating and/or rearranging hierarchical levels, be beneficial to overall language recovery in aphasic individuals ranging in severity and type?

The first objective of this investigation is to provide 21 aphasic adults of various severity levels an opportunity to achieve significant increases in the level of their communicative functioning, using a well-established, reliable treatment procedure. The second objective is to establish the most effective linguistic cueing hierarchy for various types and levels of aphasia in two treatment mediums: microcomputer/clinician-assisted treatment, and clinician-alone treatment. The third objective is to deter-

mine whether or not streamlining the treatment package can be efficacious to overall language recovery of aphasics by eliminating and/or rearranging treatment levels.

Methodology—To study treatment effectiveness, an alternating treatment design with multiple probes (single-case) is utilized. By using this type of design, baseline performance, effects of treatment, maintenance of behavior, and generalization across treatment tasks can be easily viewed. All patients received two modes of treatment (clinician and microcomputer) daily, in a rapidly alternating fashion. The microcomputer and clinician treatment packages are identical in terms of types of stimuli, modality, and randomization of presentation, and type of feedback and scoring.

Progress—Procurement of all equipment for both research sites has been completed. Final revision of the software has been completed in accordance with the VA Advisory Group recommendations. Twenty-seven patients have been identified for inclusion in the study. Twenty-three subjects have completed the Cueing Verb Treatment, while four are in process (included in the subject numbers are patients from the original CVT project). Data are currently being analyzed for the subjects who have completed the project. Dissemination activities have included oral presentations that reported the project to state, national, and international audiences.

[448] The Influence of Topic and Listener Familiarity on Aphasic Language

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Sponsor: VA Rehabilitation Research and Development Service (Pilot Project #C89-48PA)

Progress—The purpose of this investigation is to examine the influence of two situational variables on the verbal output of aphasic individuals: 1) the characteristics of the message to be communicated; and, 2) the characteristics of the listener. Thirty adult aphasics (10 in each of the syndromes of Broca's, Wernicke's, and conduction), displaying a mild-to-moderate degree of aphasia will be included. Ten normal individuals will also be included as controls.

Methodology—Each subject will be required to complete two experimental tasks, story retelling and procedural discourse. Half of the topics included in these tasks will be familiar to the subjects, and half will be unfamiliar. For the story retelling task, a "listener" will read the story aloud and the subject will immediately retell it. For the procedural discourse task, subjects will be instructed by a listener to orally produce a narrative telling how a particular procedure is done (e.g., replacing a light bulb). These two tasks will be completed twice by each subject, once with a familiar listener (spouse) and once with an unfamiliar listener (one of the principal investigators).

Subjects' verbalizations will be scored from written transcriptions of the tape-recorded testing sessions. The following verbal complexity measures will be completed: 1) mean length of utterance; 2) amount of embedding; 3) percentage that dependent clauses are of total clauses; 4) percentage that nonfinite clauses are of total clauses; and, 5) vocabulary size.

Two multivariate repeated measures' analyses of variance will be used to analyze the data, one for the story retelling and one for the procedural discourse task. Each analysis will contain one between-group factor, consisting of four levels (three aphasic subgroups and one normal control group), and two within-group factors, topic familiarity, and listener familiarity. Both the topic familiarity and the listener familiarity factors also contain two levels: familiar and unfamiliar. The dependent variables for each of the analyses will be the six measures of verbal complexity mentioned previously.

Implications—Results obtained will have important implications for professionals involved in the diagnosis and treatment of aphasic patients.

[449] Characteristics of Tracheoesophageal Voice in Four Prosthetic/Occlusion Conditions

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Sponsor: VA Rehabilitation Research and Development Service (Project #C499-RA)

Purpose—The primary purpose of the study is to examine the impact of type of voice prosthesis and nature of tracheostomal occlusion on perceptual and acoustical characteristics of tracheoesophageal (TE) speech in males. The four prosthetic/occlusion combinations used by each TE speaker are as follows: 1) Blom-Singer duckbill prosthesis with digital occlusion of the tracheostoma; 2) Blom-Singer duckbill prosthesis with the Blom-Singer tracheostoma valve; 3) Blom-Singer low-pressure prosthesis with digital occlusion of the tracheostoma; and, 4) Blom-Singer low-pressure prosthesis with the Blom-Singer tracheostoma valve. Patient variables such

as age, radiation therapy, radical neck dissection, myotomy, and whether the TE puncture was performed as a primary or a secondary surgical procedure are being catalogued to allow for examination of the influence of these variables on perceptual and acoustical aspects of TE speech. Normal speakers will serve as controls.

Methodology—The experimental protocol requires that each subject be video/audiotaped while performing a variety of speaking tasks. Each laryngectomee subject performs these tasks four times, once using each of the prosthetic/occlusion combinations.

For the perceptual portion of the study, three judge groups, varying in their knowledge of laryngectomees, view the videotapes and rate the speaking proficiency of each normal subject and each laryngectomee using each of the prosthetic/occlusion combinations on the following parameters: voice quality, pitch, speaking rate, loudness, intelligibility, visual presentation during speech, extraneous speaking noise, and overall communicative effectiveness.

For the acoustical portion of the study, audiotapes are used to extract the following acoustical information for each normal subject, and each laryngectomee using each of the prosthetic/occlusion combinations: fundamental frequency (including mean, standard deviation, and range); mean and standard deviation of jitter; jitter ratio; directional jitter; mean intensity; mean and standard deviation of shimmer; and directional shimmer. The following temporal factors are also measured from the audio recordings: number of words read per minute, total pause time, percentage of total reading time occupied

by pauses, total phrase time, number of words per phrase, and mean maximum phonation time.

Results—The results of this study are ongoing and will be reported in full when this 3-year investigation is completed in September 1991.

Implications—Knowledge about how others perceive/rate voice produced with various combinations of voice prostheses and stomal occlusion, as well as the extent to which acoustical characteristics of the resultant voice approximate laryngeal voice, will likely affect patients' choices regarding voice prosthesis and method of stomal occlusion. In addition, the research design and statistical analyses will identify voice characteristics of TE puncture patients that are the most aberrant (most different from laryngeal speakers). These are the characteristics that should be the focus of speech therapy with such patients.

[450] Chest Wall Kinematics in Alaryngeal Speakers: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #C975-PA)

Purpose—The purpose of this exploratory descriptive study is twofold: 1) to describe chest wall kinematic function using the kinematic method (a unique, noninvasive means with which chest wall function can be studied in exceptional traditional esophageal speakers); and, 2) to determine whether and how chest wall kinematics differ during speech production by traditional esophageal speakers comparable in body type, age, and level of acquisition of esophageal speech, but who differ according to the presence or absence of excessive stomal noise.

Methodology—Two groups of traditional esophageal speakers systematically perform respiratory activities and utterance tasks. Using magnetometers (electromagnetic transducer coils), the anteroposterior (A-P) displacement of the two-component chest wall, the rib cage (RC) and the abdomen (AB) are monitored. With movement, each component displaces volume, and because changes in the A-P diameters of the RC and AB are related linearly to the volume displaced by each respective part, together they displace a volume equal to that displaced by the lungs. Hence, use of the kinematic method provides physiologically-based information regarding lung volume

events with utterance in addition to information regarding the contribution of the component parts, RC and AB.

Progress—Preliminary analysis of data for 10 subjects indicates that the relative contribution of the RC and AB to chest wall displacement varies among speakers. Predominance of the AB, RC, or some combination of the two has been observed. "Excellent" esophageal speakers tended to speak while maintaining ± 5 -10% vital capacity (VC) around an end (resting) expiratory isovolume line. Lung volume change was minimal, and presumably an important reason for these speakers being rated as not exhibiting excessive stomal noise. Not infrequently, "excellent" speakers initiated speech at or below the resting expiratory level. Relative stabilization of the chest wall in a biomechanically efficient posturing likely plays an important role in dissociating respiratory and esophageal function, and presumably contributes in large part to minimizing the potential for stomal noise. During esophageal speech production by a subject who spoke with excessive stomal noise, two observations were made: 1) an inspiration of from approximately 15 to 20% VC above the end expiratory isovolume line preceded

utterance; and, 2) a respiratory "punch" was observed on the screen of the oscilloscope, in association with each word produced. Each "punch" consumed from 5 to 10% VC and the contribution of the RC to chest wall

displacement exceeded the contribution of the AB (in this subject).

Data are being prepared for further computer and statistical analysis.

[451] Ideomotor Apraxia: Recovery and Treatment

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Sponsor: VA Rehabilitation Research and Development Service (Project #C567-RA)

Purpose—The current project deals specifically with ideomotor limb apraxia associated with lesions of the left cerebral hemisphere. Ideomotor apraxia is a syndrome of theoretical importance as its study may lead to an understanding of how the brain mediates skilled movement and how skill acquisition occurs. But the study of apraxia may have important clinical implications as well. Disruption of a system that mediates skilled movement may not only affect tool use, but also may affect other forms of skilled movement such as gesture, an important communicative strategy (especially in patients with aphasia). For example, LeMay *et al.*, showed that aphasic patients use more spontaneous hand gestures during speech than non-aphasic individuals, which may represent the aphasic patient's strategy to compensate for inadequate verbal communication. In addition, the speech/language pathologist commonly uses gesture in treatment for aphasia.

Although the neuropsychological mechanism of apraxia has been studied, little is known about the recovery of ideomotor apraxia. Recovery information is particularly relevant to the clinician because knowledge of the nature of a syndrome's evolution allows the clinician to anticipate the behaviors that have the potential to change and those that will most likely remain impaired. Restitutive treatments should be directed at those behaviors that have the most potential to recover and substitutive treatments should be directed at those behaviors that are likely to remain impaired.

Since gesture is an important communication mode in the aphasic patient and impairment of praxis is a common concomitant of aphasia, it is likely that the speech/language pathologist will wish to treat ideomotor limb apraxia in some aphasic patients. Because little is known about the evolution and recovery of apraxia,

and information that pertains to recovery and syndrome evolution may be important in the selection of treatment approaches as well as predicting the patient's abilities in activities of daily living, the present study was undertaken.

Methodology—First, we wish to understand the influence of the presence of ideomotor apraxia on the use of gesture and of tools by left hemisphere brain-damaged patients. Therefore, we will analyze videotapes of spontaneously produced gestures during conversation and tool use in the natural environment in groups of apraxic and nonapraxic subjects.

Second, we will study the evolution of ideomotor apraxia with specific interest in the extent of recovery that might be anticipated and whether this recovery might be predicted by certain radiographic or behavioral indices. Therefore, performance of apraxic subjects on a test requiring gestures to command, and a gesture discrimination test will be compared at onset, 6-weeks, 3-months and 6-months post onset of apraxia. Changes in behavioral measures will be correlated with CT scan lesion volumes.

Finally, we wish to assess the effectiveness of treatment in the different forms of ideomotor apraxia. Specifically, those patients for whom apraxia persists at 6-months post onset will be administered a treatment protocol. Results of treatment will be compared across patients with different forms of apraxia.

Progress—The investigation remains in the early stages of equipment and test preparation, patient identification, and preliminary testing. Therefore, no results are available for dissemination at this time.

[452] Augmentative Communication for Intensive Care Unit Patients

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Sponsor: VA Rehabilitation Research and Development Service (Project #C563-RA)

Purpose—The inability of Intensive Care Unit (ICU) intubated patients to communicate verbally has been identified as a major stressor. Communication aids may help to alleviate the stress of this hospital experience. Despite the availability of commercially produced augmentative communication devices, there is no one system that meets the immediate needs of the ICU patient. The Intensive Care Communicator, a software program developed by Kevin Neelands (Acumen Software, 1986) for use with Apple and IBM hardware, was designed solely for use by ICU patients. The major objective of this project is to determine whether the Intensive Care Communicator program can effectively be utilized as a means of communication among intubated patients, staff, and family members.

Progress—A pretest to assist in the selection of participants has been developed. Test areas include: 1) general cognitive awareness; 2) processing efficiency; and, 3) psychological traits (introversion versus extroversion). Word lists have been modified to include phrases that are completed with selections from single word lists. Lists have been categorized with respect to pain, feelings, physical needs, general needs, general questions, responses to questions and general requests. The use of

a turbo-roller-ball has been incorporated as a hand control option (as compared with the original five-switch control). Hardware as well as software has been restored to working order. Patient testing had been restricted due to operating difficulties with both the Apple and IBM computers. Application was made to Shands Teaching Hospital at the University of Florida Medical School for permission to test ICU patients at that facility and inservices for the nursing staff have been conducted in both the medical and surgical ICUs at the VA Medical Center.

Methodology—We have begun the following procedures: 1) selection and training of Intensive Care Unit patients to use the computer program to assist communication during a period of intubation; 2) data collection and analysis; 3) ongoing modification of word/phrase lists that form the core of the Intensive Care Communicator program; and, 4) conduction of inservice training for ICU personnel.

Results—As stated, patient testing has been hindered by computer breakdown. However, electronic problems have been remedied, testing resumed, and it is hoped that the two sites will provide a patient pool.

[453] Promoting Generalized Language Use: An Analysis of Treatment and Subject Variables

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Purpose—This research program consists of three studies designed to further our understanding of the principles and procedures that may explain and produce generalization of functional communication skills in aphasic adults.

Methodology—The first study will describe the effects of the 1) number of conversational partners, 2) familiarity of conversational partners, 3) sampling procedures, and,

4) sampling environment on the relative use of a variety of pragmatic and linguistic variables by normal and aphasic adults. This study will 1) provide data relevant to contexts for assessment of communicative behaviors leading to identification of conditions appropriate for stimulus generalization probing, 2) identify areas of deficit in the conversational discourse of aphasic individuals and therefore provide data for selection of treatment

targets, and 3) provide normative data for evaluating the social validity of treatment effects derived in the experimental portion of the program.

The second phase of the program will consist of a series of direct and systematic experimental replications designed to investigate the effects of generalization training on a variety of targeted language behaviors. This phase of the project will employ single-subject experimental research designs.

The final study of this program will examine the relationship between outcome measures of generalization and subject variables, including severity of aphasia/motor speech disturbance, severity of auditory comprehension deficit, and personality factors.

Progress/Preliminary Results—Experimental stimuli for each sampling procedure employed in Study 1 have been developed and validated by 20 non-brain damaged volunteers. Linguistic and pragmatic analysis protocols have been applied to 10 disordered and 10 normal discourse samples and have been modified/adapted to meet specific project needs. Preliminary results regarding the effects of discourse elicitation condition have been reported. Experimental analyses of generalization training procedures have been reported for functional instruction-following skills and are ongoing for a variety of other speech and language behaviors.

Future Plans—Following data collection for all subjects (30) and conditions (5) in Study 1, statistical analyses

will be performed and results reported. Refinement of generalization training procedures will continue for the duration of the project.

Recent Publications Resulting from This Research

- Facilitating Generalized Requesting Behavior in Broca's Aphasia: An Experimental Analysis of a Generalization Training Procedure. Doyle PJ, *J Appl Behav Anal* 22:157-170, 1989.
- Training and Generalization of Agrammatic Aphasic Adults' Wh-Interrogative Productions. Wambaugh JL, Thompson CK, *J Speech Hear Disord* 54:509-525, 1989.
- Issues in Treatment Efficacy Research: Comments on Doyle, et al., Bourgeois and Lansing & Davis Papers. Thompson CK, in *Treatment Efficacy Research in Communication Disorders*, 223-231, L.B. Olswang et al. (Eds.). Rockville Pike, MD: American Speech-Language-Hearing Foundation, 1990.
- Conversational Discourse of Aphasic and Normal Adults: An Analysis of Communicative Functions. Wambaugh JL et al., in *Clinical Aphasiology*, Vol. 20, T. Prescott (Ed.). Austin, TX: Pro-Ed. (in press).
- Facilitating Functional Conversational Skills in Aphasia: An Experimental Analysis of a Generalization Training Procedure. Doyle PJ, Nakles KO, Goldstein H, in *Clinical Aphasiology*, Vol. 19, T. Prescott (Ed.). Boston: A College Hill Publication, Little, Brown, & Co. (in press).
- The Effects of a Time Delay Procedure on Comprehension of Verb-Noun Commands in Severe Aphasia. Oleyar K, Doyle PJ, Goldstein H, in *Clinical Aphasiology*, Vol. 20, T. Prescott (Ed.). Austin, TX: Pro-Ed. (in press).
- Effects of Phonologically-Based Treatment on Aphasic Naming Deficits: A Model Driven Approach. Thompson CK, Raymer A, in *Clinical Aphasiology*, Vol. 20, T. Prescott (Ed.). Austin, TX: Pro-Ed. (in press).
- Effects of Verbal Plus Gestural Treatment in a Patient with Severe Apraxia of Speech. Raymer A, Thompson CK, in *Clinical Aphasiology*, Vol. 20, T. Prescott (Ed.). Austin, TX: Pro-Ed. (in press).

[454] Neurogenic Communication Disorders in Remote Settings

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Purpose—Patients who suffer neurogenic communication disorders and reside in remote settings where speech-language pathology services do not exist do not receive services, or must travel long distances, or remain inpatients for protracted periods. There is a need to provide appraisal, diagnosis, and treatment for patients who live beyond existing service's reach.

We have been testing technology's ability to provide services where services do not exist. During the past 5 years, we have simulated the use of an existing treatment center's ability to provide appraisal, diagnosis, and treatment in remote settings by means of television and

computer-controlled video laserdisc-over-the-telephone. Currently, we are conducting a field trial of the computer-controlled video laserdisc equipment and methods developed in the simulation study.

Methodology—Initially, we compared appraisal and diagnosis of patients who suffer neurogenic communication disorders in three conditions: traditional face-to-face, close-circuit television, and computer-controlled video laserdisc-over-the-telephone. In addition, aphasic patients who met selection criteria were assigned randomly to one of the three conditions for a 6-month treatment trial.

Patients were appraised, diagnosed, and treated in the three conditions, and comparisons of accuracy in diagnosis and appraisal, and efficacy of treatment were made between combinations of conditions.

Currently, a field test is being conducted that compares traditional face-to-face appraisal, diagnosis and treatment with computer-controlled video laserdisc appraisal, diagnosis, and treatment. As in the simulation study, patients who suffer a variety of neurogenic communication disorders are appraised in two conditions: traditional face-to-face and computer-controlled video laserdisc-over-the-telephone. We are utilizing an existing Speech-language Pathology Center to provide, by telephone, services in two DVA Outpatient Clinics where they do not exist. In addition, an aphasia treatment trial is comparing traditional face-to-face treatment with treatment by computer-controlled video laserdisc by telephone in the DVA Outpatient Clinics.

Preliminary Results—In our simulation study, we found no significant differences in appraisal and diagnosis of neurogenic communication disorders among the three

conditions: face-to-face, closed-circuit television, and computer-controlled video laserdisc-over-the-telephone in a sample of 72 patients. A smaller sample participated in the aphasia treatment study. Essentially no differences existed among conditions in the amount of improvement obtained in a 6-month aphasia treatment trial.

Because of a significant difference in cost between television and laserdisc by telephone and the lack of significant differences among conditions in the simulation study, we elected to compare laserdisc-over-the-telephone with traditional face-to-face management in the field test. To date, 43 patients have been entered into the field test appraisal and diagnosis study, and 13 patients have been entered into the field test treatment trial.

Recent Publications Resulting from This Research

Veterans Administration Rehabilitation Research: Adult Neuro-pathologies. Kearns K et al., ASHA 49, October 1989.
 Eye, Ear, and Instrumentation. Wertz RT et al., ASHA (in press).
 The Potential of Telephone and Television Technology for Providing Appraisal and Diagnosis for Neurogenic Communication Disorders in Remote Settings. Wertz RT et al., Aphasiology (in press).

[455] Exploration of Simple Environmental Control Technology with Severely Multiply Disabled Students

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Sponsor: Bell Telephone Pioneers

Purpose—The most serious challenge posed to clinicians and teachers of severely multiply disabled and nonspeaking children is to engage students in meaningful and/or fun activities. No matter how highly qualified or how enthusiastic, staff working with these students become frustrated by the students' inability to make things work and by the students' lack of success. Most of the students were limited because they could not move or reach, did not see, had great trouble orienting themselves, and were very limited in their physical gross and fine motor movements. The students did not react with interest to "traditional" toys. Staff were encouraged to experiment with various kinds of technologies in connection with play and learning materials. Some of what was constructed used no technology to speak of, and other applications used basic technology. A simple Environmental Control (EC) unit consisting of an Ultra 2T transmitter and two power modules was used to operate a tape recorder, radio, electric train, or battery-operated toys.

Methodology—It was observed that toy placement is important. Toys should be located such that the child can easily see, hear, and touch the toys (when it is safe to do so). It is very important to arrange the situation to ensure success. Before starting the initial session, all switches and toys/appliances should be tested to ensure that they work. Regular sessions or set routines into which the switches and EC activities are integrated can help to establish a pattern of expectations on the part of student and teacher.

Results—In most instances, sensory technology provides opportunities for communication and the very important social component. The social interaction of student and teacher or of other facilitators is often crucial to the success of the technology. It was noted that the switches, toys, and appliances create a shared context for the teacher and the student. As students become able to control things, they acquire a real stake in the EC situation.

This enhances realism and this interactive discourse of student, teacher, and technological device that is relevant for the student fundamentally changes the nature of the teacher-student interaction.

We have found that technology has been a useful tool in our work with this student population of profoundly physically and developmentally disabled students. It is true that each time we developed some new materials, we tended to view these either too skeptically or too enthusiastically. While some of the students did respond with interest and curiosity to some of the adapted materials,

other students showed very little or no response at all to the materials that we thought would become immediate favorites to them.

In the course of two years' work with a population of severely multiply disabled students we found that what does not work are activities that: 1) are too repetitive; 2) elicit very little language from staff; 3) are essentially simple cause/effect: it goes on/it goes off; 4) have no sense of humor; 5) have minimal movement; 6) have no story line to expand on; 7) produce an unpleasant noise; 8) startle rather than soothe; and, 9) have no human component.

[456] Development of a Computer-Based Expert System for the Selection of Assistive Communication Devices

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Sponsor: Channel 7 Children's Medical Research Foundation of S. Australia, Inc.

Purpose—This research project aims to develop a computer-based expert system that will aid in the selection of one or more assistive communication devices for a client.

Methodology—The software used for this project is the MS-DOS Texas Instruments package Personnel Consultant Plus. The 17 features that we consider to be critical in selecting a device are: user's symbol system, input method, selection technique, output required, vocabulary size, vocabulary manipulation, portability required, price range acceptable, spelling ability, target size, vocabulary environment, vocabulary expansion capability, vocabulary flexibility required, visual acuity, visual interpretation skills, speed and accuracy, and training availability.

Progress—The current status of the project is that a user answering a number of questions will be referred to none,

one, or some of 35 communication devices. The system is currently being tested by speech pathologists within our center.

Future Plans—The system will be modified according to feedback from users. We will then conduct trials at external sites and modify it on the basis of feedback. Our intention is to produce, and regularly update, a marketable product which will be of widespread use.

Recent Publications Resulting from This Research

Development of a Computer-Based Expert System for the Selection of Assistive Communication Devices. Garrett R et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 348-349, 1990.

[457] Evaluation of Voice Amplifiers

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Sponsor: Ministry of Health of Ontario; Royal Ottawa Health Care Group

Purpose—Persons with very weak voices often require an amplification system so that they can be heard intelligibly. There are several portable battery-powered amplifiers sold for this purpose. The object of this project is to perform precise tests on the amplifiers to find out if

they perform appropriately, taking into account the needs of the users as well as the cost.

Progress—The Assistive Devices Branch of the Ministry of Health of Ontario has requested that tests be performed

on audio amplifiers being considered for the list of approved devices.

Our tests so far have shown that the bandwidths of these amplifiers are very narrow—some narrower than others. This will produce speech distortion, the significance of which will be evaluated during the coming year.

The quality of the loudspeakers are also of concern, but these are a direct consequence of most

users demanding small size and lightweight units. We are searching for optimum small and lightweight speakers which could be specified for such applications.

Poor design features have been identified in some amplifiers. For example, we have examined amplifiers with metal covers which would short out the circuit if it received just a minor dent.

[458] Developing the Role of Maxillofacial Prosthodontists in a Rehabilitation Team for Disarthric Patients

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Sponsor: *National Rehabilitation Hospital Research Center*

Purpose—The project is designed to demonstrate innovative procedures by a maxillofacial prosthodontist in the rehabilitation of stroke and head trauma patients with dysarthria and/or dysphagia. Prostheses such as palatal lifts and/or palatal augmentation are provided for patients meeting predefined criteria. These devices will serve as prosthetic aids in specific ongoing exercises of the tongue and soft palate when neurologic damage due to the underlying condition has resulted in limiting the amount and strength of motion in the tongue and/or partial or total paralysis of the soft palate. Previous experience has shown that patients considered “stabilized” may show additional improvement in muscle tone and mobility when prosthetic management is added to the treatment plan, thereby improving speech and swallowing production. Additionally, patients assisted by the prostheses early in speech therapy have been found to show improvement more rapidly as well as achieving better results.

Methodology—The research design calls for selection of 20 patients who have sustained head trauma or a cerebral vascular accident, suffer from speech and/or swallowing difficulty and who, after having received conventional speech-language rehabilitation treatment still demon-

strate significant deficits. The treatment consists of fitting oral prostheses and adjusting them during additional speech-language rehabilitation until a new level of stabilization has been reached.

Assessment of Intelligibility in Dysarthric Speech (CAIDS), diadochokinetic rates and swallowing assessment will provide data for comparisons of baseline and final status. Data will also be collected to permit analysis of changes in length of therapy required.

The systematic introduction of the maxillofacial prosthodontist into the rehabilitation team working with stroke patients and those suffering from head trauma with a diagnosis of dysarthria will be developed.

Progress—*Treatment of patients meeting selection criteria.* Almost half the subjects have been selected, treated and evaluated, and work with the remaining required number was expected to be completed by January 1991.

Integration into the hospital organization and function. The proffered service is now included in the material used when planning treatment, and constitutes a standard treatment alternative utilized by the Speech-Language Pathology Service, Occupational Therapy, and Biomedical Engineering staffs involved in patient care.

[459] Evaluation of Gestural Methods for Control of Computer-Based Communication Systems

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—There is a growing interest among the rehabilitation engineering community to devise methods by which people can interact with a computer through a combination of manual, visual, or facial gestures. For individuals who are unable to speak, a gestural method of communication and computer access may offer a more efficient method of communication. If the method of communication can be translated by computer to produce synthetic speech, the requirement that other individuals know the gestural language is eliminated.

Methodology—Two strategies for gestural control over synthetic speech are being explored: gesture recognition and phonotopic. A gesture recognition system learns and subsequently recognizes the free limb and head movements of individuals with motor disabilities. These movements are analyzed with the intent to harness the repertoire of gestures available to a particular subject, and to develop a method for computer recognition of these gestures. It is presumed that the repertoire of gestures could subsequently be mapped to various functions for control of a synthetic speech system or a computer. The gestures are recorded by utilizing techniques to develop 3-dimensional kinematic descriptions of the gestures. Three-dimensional analysis of gestures is accomplished by utilizing the telemetered rapid acquisition and computation of kinematics system developed at MIT and known as TRACK.

A phonotopic system is based on a representation of speech captured in a 2- or 3-dimensional display. Phono-

topic refers to a topological arrangement of English phonemes. Gestures are indicated by passing a pointer through the display to select targets. The pointer is controlled by a position-monitoring device. In this case, a gesture corresponds to a syllabic utterance. A phonotopic system encourages the user to associate a particular gesture with a speech utterance. The central focus of the research being conducted at MIT on phonotopic systems is to develop an understanding of the optimization criteria of syllable-based communication, and to quantitatively evaluate the phonotopic approach with other syllable-based approaches to augmentative communication.

Progress—A preliminary design of a phonotopic display has been developed and implemented. A preliminary set of experiments intended to evaluate various strategies in phonotopic displays will be conducted. An additional set of experiments which focus on the kinematic analysis of motor-disabled gestures are also intended. These experiments will utilize the TRACK system. It is hoped that these experiments will help elucidate the necessary parameters for gesture recognition.

Recent Publications Resulting from This Research

Toward Gestural Control of Synthetic Speech for Augmentative Communication. Horowitz DM, in Proceedings of the 12th Annual International IEEE/EMBS Conference (in press).

[460] Evaluation of the Functional Communicative Benefit of VIC for Persons with Chronic Global Aphasia

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—VIC is a visual language technique for individuals with severe aphasia, developed at the Boston VA Medical Center and first implemented on a computer at

the Palo Alto VA Medical Center. This study undertakes to evaluate the impact of VIC training on a number of aspects of aphasic VIC users' language and communicative

function: 1) relative benefit, in terms of improvement in aphasic symptoms, of VIC versus natural language training; 2) relative communicative effectiveness of VIC-trained versus traditionally-trained patients; 3) characterization of VIC "competence" acquired compared to language competence regained by traditionally treated patients; 4) effect of alternative techniques on the patient's sense of well-being; 5) predictive value of patient characteristics for functional communication; 6) predictive value of patient characteristics for VIC acquisition; and, 7) characterization and comparison of VIC performance with natural language performance of VIC-trained patients.

Progress—Software has been written in C language which emulates the VIC user interface and provides improved flexibility, customizing ease, and lexicon capacity. Software to provide a planning interface for the specification of training and testing parameters, and a data acquisition component, is under development.

Methodology—Adults with severe expressive or global aphasia (at least 6 months or more post-stroke) with unilateral lesions, and not currently pursuing speech/language therapy, will be enrolled in the project.

Repeated assessments of aphasia prior to enrollment in the study will be carried out to assure a stable baseline. Patients will then be randomly assigned to control (traditional therapy) and experimental groups (VIC). Pre- and post-measures will be carried out in regard to the questions posed above.

Results—A pilot study with two patients with chronic severe expressive aphasia and moderate comprehension involvement has been completed. Review of the gains made by these individuals and of the additional cases reported in the literature indicate that there are important differences among individuals within the population of severely aphasic patients, including differences among patients with similar relative sparing of comprehension. These differences affect the extent of benefit (e.g., VIC performance), as well as the type of benefit (gains in functional speech, gains in reading comprehension, benefit to state of mind).

Future Plans/Implications—The study outcome will include guidelines for selecting patients for VIC training, for structuring the system and training, and for modifying the technology. It should also provide indications for new directions of research.

Recent Publications Resulting from This Research

Computer Interface for Severe Language Disability. Goodenough-Trepagnier C, in *Designing and Using Human-Computer Interfaces and Knowledge Based Systems*, 420-427, G. Salvendy, M.J. Smith (Eds.). Amsterdam: Elsevier Science Publishers, 1989.

VIC Performance—Effect of Grammatical Category. Goodenough-Trepagnier C, in *Proceedings of the 12th Annual RESNA Conference*, New Orleans, 143-144, 1989.

Functional Communication Using VIC. Goodenough-Trepagnier C, in *Proceedings of the IEEE Engineering in Medicine and Biology Society*, Philadelphia (in press).

[461] Early Intervention with Globally Aphasic Stroke Patients Using a Computerized Visual Communication Technique

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The experimental intervention developed in this project (E-VIC) is a computer-guided, computer-presented training program designed to be used with acutely, globally aphasic patients. Code written in C language for a Macintosh (SE or Plus) supports presentation of line drawings on a full-page display, and instructions to the clinician (on the monitor) as to the object and/or action stimulus to present. The stages of training include operation of the mouse interface, selection of the picture which matches a single stimulus (from among a field of choices), selection of the appropriate picture after

delay, selection of a sequence of pictures after delay, and other stimulus types.

The primary goal of the project is to determine whether training with the experimental intervention has an effect on rate and level of recovery of language function.

A second goal is to relate indices of E-VIC performance to patient characteristics and lesion data, and to determine the relation of these, and interactions between them, to recovery. The characterization of patients' learning strategies is also a goal of the study, based on analysis

of errors and cursor path data automatically recorded by the program.

Methodology—Subjects are patients in the acute stage of evolution of their aphasia, within 6 weeks of a post-cerebral vascular accident (CVA), who are severely speech- and comprehension-impaired.

The design uses an experimental group and a control group of subjects, with patients assigned randomly to one or the other treatment. Subjects in both groups receive an equal number of sessions (up to 20) over a period of 3 to 5 weeks, with E-VIC for experimental group members and standard therapies for control group members, both implemented by speech/language clinicians.

Preliminary Results—A preliminary study of feasibility of the experimental intervention involving eight patients was published. Patients are all able to operate the system. Almost all patients progress to successful performance in selecting from among three choices. Seventeen additional patients have since completed the experimental or control training. Despite the diagnosis common to all subjects of severe, global aphasia, there is great inter-subject variability in patients' success using E-VIC. Some patients progress rapidly through the advanced levels, dealing with conditions as complex as "hidden context" (two

objects are displayed, then removed; after a delay, the former location of one of the objects is indicated; the subject's task is to select the corresponding picture from a field of six which are then displayed on the monitor). Others take several sessions before they select from among two alternative pictures, the one corresponding to the object displayed in front of them.

Preliminary findings suggest that greater left hemisphere preservation is related to more rapid E-VIC progress. One particular subtest of the clinical aphasia examination used (map location) was also related to greater success with the training.

Data collection is continuing, and results will be analyzed once there are at least 20 patients in each group.

Implications—The success in progressing through E-VIC experienced by these severely involved patients indicates that it is possible for acute global aphasics to have a progressive, rewarding learning experience despite the severity of their impairments, within the first weeks of recovery.

Recent Publications Resulting from This Research

Development and Testing of a Computerized Language Intervention for Acute Global Aphasia. Goodenough-Trepagnier C, Alexander MP, Baker EH, *Assist Technol* 1(4):81-90, 1989.

[462] Evaluation of Handheld Prostheses for Speech Therapy

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Sponsor: *National Institute on Deafness and Other Communication Disorders, National Institutes of Health*

Purpose—Speech-language pathologists (SLPs) have minimal tools, beyond hierarchical exercise and instruction, to assist the patient to produce intelligible speech when there has been neurological or structural damage to the lips, tongue, palate, and/or larynx. Treatment may be lengthy and the outcome less than optimal. Further, it is expensive since it is a "one-on-one" patient-SLP process.

We have developed a set of training aid devices to help in speech rehabilitation of patients with oral-motor disorders of speech secondary to stroke, head trauma, or laryngectomy.

These experimental training aids have been used clinically by the principal investigator when involved in such rehabilitation. This clinical experience has shown

that the learning process is speeded up with the use of these devices; the SLPs have found them easy to use, the patients have accepted them readily. It has also been found that patients can use the devices independently for additional practice outside of treatment sessions.

This project is Phase I of research to evaluate the efficacy of the devices as part of speech therapy for improving intelligibility. The devices are designed for patients with labial and/or lingual problems in the production of linguo-alveolar and/or linguo-velar sounds or plosive and fricative consonants. Patients recovering from stroke or head trauma frequently exhibit such problems, while laryngectomees with esophageal speech may have labial and lingual problems in producing adequate air injection.

Progress/Methodology—Patient selection began in September 1990. Fifteen stroke and head trauma patients, and five laryngectomees with significant residual intelligibility problems after reaching stabilization will be given 20 double sessions using the devices. Standard

tests of intelligibility will be administered at intake, mid- and end-points. Dimensions of air injection capacity will also be assessed by oscillography. Scoring will be blind, and the statistical significance of change in scores tested.

[463] Language Organization Studied by Cortical Stimulation

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Purpose—This is a study of the functional and neuro-anatomical architecture of language processes based on the reversible impairments produced by direct electrical cortical stimulation. Current neuropsychologic and neuroanatomic models all posit that language abilities are mediated by smaller, distinct processing components with specific interconnections. Some of these models specify the neuroanatomic loci of these components. The bulk of their evidence has been derived from studies of patients with fixed lesions and stable language impairments. However, this source has been part of the reason why these models have proven to be difficult to test adequately: accidentally placed, relatively large, irreversible lesions make it difficult to fractionate the deficits that are actually present, or the true role that is played by those functions that remain.

Direct, focal, electrical cortical stimulation has demonstrated the potential for overcoming some of these difficulties by being able to induce multiple, selective impairments of functions with complete reversibility.

Methodology—We will investigate the structure of reading, visual confrontation naming, and auditory comprehension through stimulation-induced deficits. Studies of

static deficits on these tasks have proven to be very productive despite their limitations, and therefore should be particularly informative when deficits can be induced reversibly, and when different patterns of deficits can be produced in the same subject at different sites. Subjects will be patients with subdural electrode arrays implanted over the peri-Sylvian language regions; we will seek to determine the nature of the deficit caused by stimulation, and establish optimal stimulation parameters.

The second part of the study will be single case studies of deficits found in clinical testing to establish: 1) what components subserving task performance are impaired; 2) how these components are interrelated; and, 3) whether these relationships are the ones predicted by current theory or whether alternative representational or processing models are necessary.

The third part of this proposal will relate the data on component impairments at specific cortical stimulation sites to cortical maps, by patient and by patient group.

Implications—These data will make a unique contribution to scientific and medical knowledge of language processes and of their cortical representations.

[464] Application of Automatic Phoneme Analysis to the Assessment of Motor-Impaired Speech

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Sponsor: *Natural Sciences and Engineering Research Council of Canada*

Purpose/Methodology—Various tests are used in the clinical evaluation of speech disorders caused by motor system impairment. Our purpose was to determine the feasibility of applying automatic phoneme analysis to

articulation testing of motor-impaired speech. One area of testing involves evaluating the articulation abilities of the individual. Typically, the patient is required to read a list of words, while the clinician judges the articulation

of certain sounds or phonemes in the word as normal, distorted, substituted by another, omitted altogether, or combined with another.

Because of the subjective nature of this type of analysis, results are not always consistent. Also, it is difficult to objectively monitor subtle changes in articulation when evaluating the effect of a particular speech therapy program.

Progress—The feasibility of applying automatic phoneme analysis to articulation testing of motor-impaired speech has been investigated. In consultation with the Speech Pathology Department of the Forest Hill Rehabilitation Centre, an articulation test has been devised consisting of 24 monosyllabic words. After the subject is prompted to say each word, the acoustic speech waveform is digitized and stored on a PC-type computer. Features based on

formant frequencies and normalized energies are then extracted to classify the phonemes of each test word. The phoneme sequence uttered by the subject can then be compared to the expected sequence to determine the errors that have occurred.

Results/Implications—Preliminary testing of the system has been conducted with both normal and motor-impaired speech. The results show that this approach to articulation testing is feasible, and with further development, may become a useful tool in the evaluation of motor-speech disorders.

Recent Publications Resulting from This Research

Automatic Articulation Testing of Motor Impaired Speech. O'Neill PA, Lovely DF, Scott RN, in Proceedings of the Canadian Medical and Biological Engineering Conference, Toronto, 61-62, 1989.

[465] Determinants of Intelligibility in Dysarthric Speech

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Sponsor: *Nemours Foundation*

Purpose—This project will conduct studies of the articulatory, acoustic, and perceptual characteristics of dysarthric speech. The goal of this research is to determine characteristics that are most disruptive to intelligibility. Dysarthria may involve a variety of deficits in the control of articulator motion including, for example: rigidity, imprecise movement, unusually slow movement, and an impaired ability to coordinate the relative timing of motion for different articulators. Some of these deficits may prove more disruptive to overall speech intelligibility than others. Moreover, different deficits may affect the intelligibility of particular phonetic segments in different ways.

Methodology—Perception experiments are planned to assess the intelligibility deficits associated with various

forms of dysarthria, both in overall terms, and in terms of the effects on specific speech segments. In these experiments, digital signal processing techniques will be used to systematically alter specific characteristics of recorded dysarthric speech that are targeted for study, while leaving other characteristics unaltered. In particular, the signal processing will be used to match dysarthric productions to normal productions of test words on a single experimental dimension. Different experiments are planned to explore different "dimensions," such as syllable timing, vowel color, and formant transition rate. In this way, it will be possible to evaluate the relative importance of each dimension in determining the intelligibility of dysarthric speech.

[466] Special Projects and Demonstrations for Providing Speech Recognition Vocational Services to Individuals with Severe Disabilities

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Sponsor: *Office of Special Education Programs, U.S. Department of Education*

Purpose—A center on speech recognition and its application to vocational rehabilitation has been established at Tufts University School of Medicine through a new 3-year grant from the Rehabilitation Services Administration. This Center seeks to demonstrate a comprehensive rehabilitation technology service delivery model to increase the availability of reliable and durable assistive technology that addresses the complex technology-related needs of individuals with disabilities. The Speech Recognition Center will package the employment model so that it will be available nationwide. The program will go well beyond the traditional approaches to applying speech recognition to rehabilitation, which often results in the purchase of a device, but not employment. We plan to demonstrate an attractive and cost-effective alternative for the rehabilitation of individuals with severe disabilities.

The individuals served by this program will have severe physical impairments due to a variety of neuromuscular disorders and visual impairment.

Methodology—The Center will work in collaboration with the Massachusetts Rehabilitation Commission, the Massachusetts Project with Industry, Kurzweil Applied

Intelligence (Waltham, MA), the Massachusetts Commission for the Blind, and the Perkins Project with Industry. This collaborative approach has been designed to match the vocational strengths of individuals with severe disabilities to the employment opportunities in Massachusetts. Large vocabulary speech recognition technology manufactured by Kurzweil Applied Intelligence will provide the individuals served by this program with the necessary means to access a computer to accomplish a job.

A Vocational Rehabilitation Advisory Panel and an Employer Advisory Panel will be formed to assure that staff develop a practical vocational rehabilitation model which realistically addresses both the client's and employer's needs. The Rehabilitation Advisory Panel will help establish a client referral base and a method for identifying client strengths. The Employer Advisory Panel will take an active role in identifying job opportunities for the clients served by this program.

The Speech Recognition Center staff will also develop a Vocational Rehabilitation Counselor's Guide to speech recognition. This is seen as essential to the successful application of the outcomes of this technology to serve as many individuals as possible.

[467] Development of a Throat Microphone

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Sponsor: *The Rehabilitation Centre*

Purpose—Throat microphones are used to amplify weak voices as a result of surgery. Most of the microphones used are not well accepted by the subjects because of their size and appearance. A new kind of throat microphone was developed which can be used with most of the commercially available amplifiers.

Progress/Results—A neck band was made and a microphone receptacle was attached on it. The microphone

can be removed easily and the neck band can be washed as needed. The head of a good quality electric condenser microphone was encapsulated in a small compartment which mates with the receptacle on the neck band. The battery compartment was fixed near the plug and the unit is used with a commercially available audio amplifier.

C. Vision Impairment

[468] Motorized and Autofocus Control Systems for Telescopic Low Vision Aids

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Sponsor: VA Rehabilitation Research and Development Service (Project #C557-DA)

Purpose—Many visually impaired individuals use miniature telescopes to provide magnification of near and distant objects. These devices are typically hand-held or mounted in spectacle frames, and focus is usually achieved by twisting the outer barrel. Unfortunately, users often encounter problems while using telescopes, many of which can be traced to the twisting nature of the focusing operation. The most frequent problems include: 1) loss of target from the field of view; 2) blurring due to jiggle; and, 3) reduced ability of persons with muscular problems, arthritis, or peripheral neuropathy to manipulate the device. A potential solution to many of these problems is to motorize the focusing process and make it a single-handed operation. The purpose of this project is to develop and test four telescope systems that incorporate two levels of motorized focus control.

Methodology—In the first level of motorized focus control, we will add a simple motorized focus control system (motor, drive train, power unit, and controls) to hand-held and spectacle-mounted telescopes. In the second level, we will use existing autofocusing camera technology and/or an autofocusing system we devise to construct autofocusing hand-held and spectacle-mounted telescopes. All prototypes are being evaluated in the laboratory and

in the field. Field-testing involves comparing performance between traditional hand-focus telescopes, motorized-focus telescopes, and the autofocusing telescope on target localization and identification tasks. Visually impaired individuals, who are experienced hand-focus telescope users, serve as subjects. We will examine the issue of training time versus performance with the traditional and prototype devices.

Progress—During the first year of this project we constructed three second generation prototype motorized-focus telescopes of 4, 6, and 8X magnification power. These are hand-held devices. Motorization of focus was achieved by adding miniature motors, geared drive trains to effect telescope barrel movement (mechanism of focus), batteries, and a two push-button control system to off-the-shelf Keplerian type hand-focus (manual) telescopes. These second generation devices are smaller and lighter than prototypes developed and tested in a pilot study. In addition, we have constructed two autofocusing hand-held telescopes by modifying autofocusing camera lenses. These devices have variable magnifications from approximately 2.5 to 4.5X and 6 to 10X. The motorized-focus and autofocusing telescopes are being tested in the lab and field-testing has begun.

[469] User Interface Environment for Visually Handicapped Computer Users: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #B986-PA)

Purpose—It is estimated that there are approximately 500,000 totally blind individuals in the United States, of whom an estimated 50,000 are veterans. Approximately 1.5 million Americans of impaired vision are classified as legally blind, including perhaps 200,000 veterans. Due

to the general aging of the population, degenerative diseases of the eye are becoming increasingly predominant. Previous research conducted by the principal investigators attempted to identify the needs of both the general visually handicapped population and a select group of

blind individuals that use adapted computers. This pilot project attempts to further our understanding of the true needs and functional requirements of the selected blind computer users, since they can possibly be used as a model for the population in general.

Important needs of expert computer users are to be able to: 1) efficiently enter text; 2) review text acquired by optical character recognition; and, 3) work within an environment that can adapt to their unique handicaps. These needs can be partially met by existing adapted computers, although these computers were originally developed to be used by sighted individuals. The methods by which these computers have been adapted for use by blind people have in many cases required the user to conform to many artificial constraints to accomplish most tasks, resulting in the user having to memorize difficult sets of key strokes or push special function keys on the edges of the keyboard. The objective of this pilot project is to formalize the specifications of a text editing and review environment that is intuitive, efficient, integrated, and adaptable.

Methodology—Over the last two decades, the continuing development of graphical user interfaces has shown the benefits of having a consistent and intuitive user environment. User interface should be integrated with the basic behavior of a computer in such a way that most basic actions done repeatedly in different programs are always accomplished in the same intuitive manner. Applying this concept to the needs of visually impaired computer users has led to the development of a blind user interface simulation environment whose basic functionality was derived

from information learned in the expert user's survey, and the extensive experience of the staff at the Western Blind Rehabilitation Center (WBRC).

Effective computer adaptation requires the use of additional devices and functionality. Through the use of a new style of text navigation device called the roller-bar, it will be possible to improve the efficiency of the user interface. This device allows a user to move through text, with feedback provided by tones and speech, without having to remove their hands from the keyboard or fingers from the home keys.

Upon completion of the simulation environment, an evaluation will be conducted using a representative group of the target population. From the user-evaluation feedback, it will be possible to modify the simulator and then check its usefulness.

Progress—This project has generated a list of the useful functions necessary for the environment of a blind computer user. A preliminary mockup of some needed basic features has been completed in HyperCard on the Macintosh computer. This mockup was evaluated by a staff member at WBRC. From this experience, a more complete simulation environment has been developed. Plans are now being made to evaluate the simulator upon its final completion, and to publish the results.

Results—The preliminary results have shown that an effective text manipulation environment for blind computer users can be developed that does not require users to remove their fingers from the home keys or to memorize nonintuitive key inputs.

[470] Development of the Family Training Program Curriculum in Low Vision

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Sponsor: VA Rehabilitation Research and Development Service (Project #C5I2-RA)

Purpose—This project was designed to study the low vision component of the family training program at the Department of Veterans Affairs Blind Rehabilitation Centers. The objectives were to: 1) develop and refine competencies in low vision rehabilitation for family members of veterans receiving low vision services; 2) develop and assess the quality of teaching material and methods to insure that family members acquire desired knowledge and skills; 3) develop an evaluation method-

ology which will allow staff to assess the effectiveness of the family training program in low vision.

Progress—Objective 1. The curriculum was written by the project and Blind Rehabilitation Center staff and evaluated by an advisory committee composed of the low vision supervisor and social worker of each of two blind rehabilitation centers, a visually impaired veteran and family member (both of whom attended the program),

and two curriculum specialists. After specific observable, measurable competencies were written, the advisory committee rated the importance and ability of each competency to be achieved. Competencies were revised and modified, and the curriculum was disseminated to the staff of the blind rehabilitation centers.

Objective 2. The project staff developed a library of existing materials (presently being used in the program), and added to it by searching for materials not presently utilized, but available. Over 100 references related to low vision (from specific eye pathology to use and care of low vision aids, and psychosocial concerns) have been compiled into a "Resource List" for use by instructors in the low vision services of the blind rehabilitation centers. The list includes information for professionals (i.e., readability level of the material, number of pages, cost, whether the material is available in braille, large print, or cassette, where it may be ordered, etc.). A 25-minute videotape entitled, "A Vision of Independence," on making environmental modifications in the home, was developed by the staff and is presently available to the blind rehabilitation centers. The tape was developed because the advisory committee noted a need for a self-training method on making environmental modifications, due to a lack of staff time to cover this competency. The videotape can be shown to family members, along with a supplement that discusses the points covered and

suggests ways that the family member can implement these points at home.

Objective 3. An evaluation methodology was developed which allows the low vision service staff to objectively assess the effectiveness of the program. The methodology utilized does not "test" the family member, but allows the family member and low vision staff to work together to assess the program, and insures that all information has been provided and is understandable. A questionnaire was designed to be sent to the family member prior to entering the program. The family member daily dates and completes the answers to questions, so that project staff can ascertain when information was received. A follow-up questionnaire can be sent after program completion.

Results/Implications—The curriculum, teaching materials, and evaluation that have been developed will assist the staff of the low vision clinics in providing individualized training programs for the family members of visually impaired veterans. The "Resource List" will assist staff in amassing and utilizing appropriate teaching resources. The compilation of the list pointed out to the staff the importance of developing written materials of lower readability levels for visually impaired veterans and family members. The videotape fills a gap identified by the staff of the Blind Rehabilitation Centers for teaching materials on environmental modifications in the home.

[471] Environmental Information Needs for Wayfinding by Special Populations

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Sponsor: VA Rehabilitation Research and Development Service (Project #E561-RA)

Purpose—Independent travel is a hallmark of effective functioning in everyday situations. Although the skills involved in traveling to and from environmental destinations are taken for granted by a large portion of the populace, the development of these skills represents a critical challenge for significant groups of mobility-impaired individuals. To a significant extent, the acquisition and successful application of mobility skills depend upon access to environmental information.

Research is needed to establish guidelines for determining the form and content of requests for wayfinding information that is most appropriate for a given environment. This research will establish a set of guidelines and a rule base for determining the form and content of

requests for wayfinding information that is most appropriate in a given environment and for a given population. Assessment of information needs of a variety of populations of people will lead directly to the development of a data-based scheme for accessing such information. This assessment is intended to be incorporated into an automated interactive system to assist a variety of travelers, including visually impaired individuals, older adults, and individuals with various disabling conditions.

Methodology—*Phase 1: Development of Environmental Information Base(s).* This phase involves the collection and organization of data concerned with the environmental information needs of six groups of 14 participants

each. Data collection will take place during two way-finding exercises, one outdoor exercise and one indoor exercise. The six groups are as follows: 1) legally blind (20/200 acuity to light perception) adults aged 25 to 60 years; 2) totally blind (no light perception) adults aged 25 to 60 years; 3) partially sighted (20/70 to 20/200 acuity) adults aged 25 to 60 years; 4) normally sighted adults confined to a wheelchair and aged 25 to 60 years; 5) adults aged 65 to 80 years who are not visually or mobility impaired; and, 6) a control group of adults aged 25 to 60 years who are not visually or mobility impaired.

Participants will be taken to the beginning of the route and instructed to ask questions that will give them information on how to get to the end by way of a prescribed route. They must ask specific questions that will reveal the type of information needed and the amount needed at various points along the walk. As the participant walks along the route, the experimenter will record the participant's path of movement on a map of the area. Following the trip, participants will provide a complete and accurate description of how to get from the beginning

to the end of the route. An audiovisual recording of participants' verbal and locomotor behavior will be made on the trips and during the direction-giving procedure at the completion of the trip.

Phase 2: Assessment of Environmental Information Base(s) as Wayfinding Aids. This phase of the project will determine the usefulness of the hierarchically organized environmental information schemes constructed in Phase 1. In the context of a wayfinding exercise, participants' need for information will be addressed exclusively by an experimenter using the hierarchical scheme in menu format. In summary, participants will be able to access specific categorized information only.

Progress—At present, routes have been developed. The indoor route will take place in the Atlanta VA Medical Center and there will be two outdoor routes, one in a residential section of Decatur, GA and another on the campus of Agnes Scott College (also in Decatur). Pilot work has been completed on all the routes. Scoring techniques, permission forms, and protocol are currently being refined. Testing of subjects began in Fall 1990.

[472] Development and Validation of Criteria for Task Safety in Blind Mobility

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Sponsor: VA Rehabilitation Research and Development Service (Project #C585-RA)

Purpose—The primary product resulting from this project will be a set of criteria, the knowledge base for Orientation and Mobility (O&M) task safety, generated by the best professional judgment of the field. The secondary product will be an expert system, based on that knowledge base, which will be a useful pedagogical tool for university training programs and a decision-making tool for clinical service delivery. It will also serve as an instrument for the identification of areas of need where new devices or training techniques are needed.

Early in the history of O&M, most clients were young, relatively healthy, and "simply" visually impaired. At the present time, there is an increasing trend for the clients of the Department of Veterans Affairs Blind Rehabilitation Centers (BRCs) to be elderly and to experience age-related multiple impairments. Because of this, evaluation of the client and his or her ability to safely perform a specific O&M task has become much more complex.

For example, clinicians must take into account an individual's degree of remaining vision, other sensory abilities, cognitive and physical status, and personality variables. These attributes of individuals must be evaluated in a variety of travel situations which range from movement in familiar indoor space to travel in highly complex, unfamiliar urban environments. The O&M specialists are required to make decisions concerning the capabilities of clients on a continuous basis, without any recourse to a standardized body of professional knowledge. Prior to the Hill and Ponder (1976) and the Welch and Blasch (1980) text books, all O&M knowledge was exclusively in the heads of the "experts." Now O&M professionals have general information, but find themselves lacking specific information regarding which competencies are required for a given client in a given situation in order to achieve a reasonable degree of safety.

Progress/Methodology—A conference of experts in the field of O&M (experienced with multiply handicapped individuals), was convened at the Atlanta Research and Development Center in 1988. From this meeting, a complex matrix of O&M tasks, environments, skills, and functional prerequisites (sensory, motor, and cognitive) was generated. While this matrix cannot be validated experimentally, this project seeks to refine and validate it as a representation of "best professional judgment."

This task will be accomplished in three phases. The first will be the incorporation of the matrix into a knowledge-based expert system, which will be designed to determine if an individual with specified training and specified sensory, motor, and cognitive function can accomplish specified O&M tasks in specified environments with an acceptable level of safety. Once a prototype system is developed and demonstrates reliable and valid

performance, the system will be used as a tool to achieve criterion consensus with a much larger panel of experts. Areas of disagreement will be targeted for expansion and/or refinement of the knowledge base in this second phase of the project. In the third and final phase, the final system will be subjected to reliability and validity testing. During this period, it will be evaluated in University O&M Instructor Training Programs, where it will be used as an adjunct to practicum experience by students. It will also be tested in VA Blind Rehabilitation Programs where it will be evaluated as a clinical decision-making tool. Between these two settings, we anticipate literally thousands of configurations of tasks and users to be tested and evaluated.

A database of functional limitations causing negative decisions with no available options (either device or training) will be maintained in order to identify areas of need for research.

[473] Relationship of Auditory Skills to the Mobility of Blind and Visually Impaired Individuals

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C438-RA)*

Purpose—The primary goal of this project is to determine how and to what extent auditory skills contribute to the mobility of persons with low vision and blindness. A secondary goal is to determine how the contributions of audition to mobility differs for special populations who, in addition to have a visual impairment, are elderly, hard-of-hearing, and/or users of hearing aids. A more complete knowledge of how auditory skills contribute to the mobility of visually impaired persons would be valuable in designing more cost-effective mobility training programs. A better understanding of the benefits and disadvantages of hearing aids in mobility training should also encourage the development of training and travel practices which take best advantage of hearing aids and the multiply-impaired person's residual hearing.

Methodology—Changes in mobility, gained through mobility training, are being measured and related to auditory skills and capabilities. Auditory capabilities which contribute to mobility are being assessed by measuring performance in a battery of auditory tests immediately before and after mobility training. Changes in auditory capabilities for individuals who receive mobility training will be compared to those of control subjects who receive

no mobility training, but undergo the same test procedures over comparable time periods.

Six groups will be compared. The groups differ on type of visual impairment (low vision versus blindness), age (and hence also high-frequency hearing ability), and use of a hearing aid. Measures of residual vision, general intelligence, personality, visually impaired travel experience, and demographic factors will also be collected. These measures will be correlated with auditory skills and mobility performance to determine how individual differences on these factors affect the use of audition in mobility and success in mobility training.

Progress—During the first year of this project, a specialized auditory test facility was designed, fabricated, and tested. The facility is capable of performing 10 highly specialized psychoacoustic tests, as well as standard audiological tests. Test procedures were designed for each of the auditory tests and pilot-tested with blind and visually impaired veterans. Equipment was assembled and test procedures developed for assessment of residual vision and indoor and outdoor mobility performance. Instruments were also developed or procured for collection of data on demographic factors, general intelligence,

personality, and visually impaired travel experience. Data is currently being collected at the Southeastern Blind Rehabilitation Center at the VA Medical Center in Birmingham, AL, and at several colleges. Automated data analysis programs are being developed and tested at the Rehabilitation

Research and Development Center at the Atlanta VA Medical Center which is located in Decatur, GA.

Preliminary Results—Testing is underway with no data analyzed.

[474] Development of an Objective Measure of Orientation Skill: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C995-PA)*

Purpose—We propose to develop a separate measurement scale of orientation ability with the following characteristics: 1) demonstrated validity and reliability; 2) appropriate for use by orientation and mobility instructors; and, 3) of reasonable generality. “Appropriate for use by orientation and mobility instructors,” means the measure must require less than one hour to administer; be independent of specific settings; and lend itself to reliable, quick, and unbiased scoring. “Generality” refers to what is measured when we claim to measure orientation skill. We plan to measure the overall ability to orient, rather than a specific manifestation of this skill, such as knowing where north is or being able to indicate straight ahead. In addition, we propose to demonstrate that the measure developed can be used reliably and practically by orientation and mobility instructors.

Methodology—The first phase of this study involves exploring and refining definitions of orientation, translating these into orientation assessment tasks, and pretesting those tasks with a few blind subjects. In phase two, we will conduct a formal experimental test of the orientation tasks to determine their usefulness, reliability, and internal factor structure. In the third phase, we will demonstrate that orientation and mobility instructors can use this orientation test.

Progress—Data collection has been underway for 8 months. We are now working on statistical analyses of the data. To date, several computer programs have been developed for data analysis. The testing of subjects continues.

[475] Identification and Classification of the Career Transition Problems of Blind and Visually Impaired Youth in Transition from School to Work

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Sponsor: *National Institute on Disability and Rehabilitation; Mississippi State University*

Purpose—The purpose of this project is to: 1) identify and classify the career transition problems of blind and visually impaired youth in transition from school to work; and, 2) outline strategies which can be used by youth agencies, service providers, families, and employers to assist youth in making successful transitions.

Methodology—Sample data were collected from two service agencies noted for having successful transition

programs for youth who are blind and visually impaired. At each site, interviews were conducted with administrative personnel; service providers such as rehabilitation counselors, orientation and mobility specialists, and vocational instructors; parents; youth who are blind and visually impaired; employers; and community support personnel. Qualitative analyses of the collected data were conducted to define the career development problems faced by youth in their transition from school to work in

terms of mastery of career development tasks. A conceptual framework linking strategy to the career development problems was formulated.

Progress—Data collection and analyses are complete. An annotated bibliography of selected readings concerning youth with vision disabilities and their transition from

school to work, a technical report, and an executive summary are in press.

Results—Results of the study will be available from the Rehabilitation Research and Training Center on Blindness and Low Vision in early 1991.

[476] Identification of Differential Costs and Time Usage of Blind and Visually Impaired Persons and the Vocational Rehabilitation Process

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Sponsor: *National Institute on Disability and Rehabilitation Research; American Foundation for the Blind; Mississippi State University*

Purpose—The aim of this project is to answer the following research questions: Are there differential monetary costs and time utilization patterns for blind and severely visually impaired persons, and in what categories do these differential costs and time utilization patterns occur? Are they associated with particular lifestyles, life stages, and environments?

Methodology—Two hundred and thirteen people with visual disabilities were interviewed in the four seasons of the year to reflect seasonal differences in activity and time usage; each interview occurred on a different day of the week to reflect differences in time and money usage during the work week, and on Friday, Saturday, and Sunday.

Similar information was collected through interviews of 152 sighted, nondisabled peers to establish a comparison group. Information was collected on personal factors, role factors, environmental factors, and resource factors.

Progress—Collected data are being analyzed. Results of the data analysis will be interpreted in terms of the differential monetary costs and time utilization patterns for persons who are visually disabled as compared with their sighted peers.

Results—Results of the study are available from the Rehabilitation Research and Training Center on Blindness and Low Vision.

[477] Differential Costs and Time Usage of Blind and Visually Impaired Persons and the Vocational Rehabilitation Process

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Sponsor: *National Institute on Disability and Rehabilitation Research; American Foundation for the Blind; Mississippi State University*

Purpose—The purpose of this project is to answer the following research question: Are there relationships among the differential expenditures and time usage patterns associated with blindness and visual impairment and the rehabilitation process? The goals of the data analyses will be to determine the cost-benefit of rehabilitation services by measuring the resulting reduction in the cost of disability; to identify postdisability costs, both monetary and nonmonetary, which are work disincentives;

to identify the reductions in monetary and nonmonetary costs to the person with a visual disability which result from rehabilitation; and to identify unmet rehabilitation service needs.

Methodology—Data were collected through case file reviews and subsequent interviews of 112 people with visual disabilities who were served by 4 public rehabilitation agencies in 4 states. Collected data are being analyzed

and compared to results from an earlier study of time and money usage patterns of people who are visually disabled in terms of rehabilitation contributions and in comparison with nondisabled persons.

Progress/Results—Collected data are being analyzed in terms of rehabilitation contributions and comparisons with nondisabled persons, and results of the study are expected to be available in 1991.

[478] Identification of Differential Characteristics of Sites Selected or Rejected by State Licensing Agencies for the Operation of the Randolph-Sheppard Business Enterprise Program

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Sponsor: *National Institute on Disability and Rehabilitation Research; Mississippi State University*

Purpose—The purpose of the study is to address the following research question: Is there a relationship between sites selected and sites rejected for operation of Business Enterprise Program (BEP) facilities and the geographic location, size of business, and additional site and agency characteristics?

Methodology—A review of the literature on site selection standards used by state licensing agencies in the administration of the BEP and similar private business enterprises was conducted. The literature addressing the relationship of site selection standards to the career development of blind and severely visually disabled persons was also examined. State licensing agencies from four states chosen from two Randolph-Sheppard Act

(RSA) regions which represent both large and small BEP programs participated in the study. Data were collected from the State Licensing Agency records with reference to site selection, and BEP directors were interviewed.

Progress—Collected data have been analyzed. Interpretation of the data analyses and development of recommendations for policy, practice, and future research are complete.

Results—Results of the study were published by the Rehabilitation Research and Training Center on Blindness and Low Vision. The report, *The Randolph-Sheppard Business Enterprise Program: Site Selection*, is available in print or on audiocassette for \$10.00 per copy.

[479] Computer Access Technology for People with Severe Visual Disabilities: Development, Evaluation, and Dissemination of a Knowledge-Based Expert System

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Sponsor: *National Institute on Disability and Rehabilitation Research; Mississippi State University*

Purpose—The purpose of this project is to address the employment problems which people with visual disabilities face because of their lack of access to information in an information-based economy. The development, evaluation, and dissemination of a computer-based expert system, the Computer Access Technology: Knowledge-Based Experts System (CAT:KBES), will assist rehabilitation specialists to identify appropriate access technology

for their blind or visually impaired clients. The program is intended to assist in the decision-making process for the selection of access devices for the particular needs of visually impaired individuals and their specific work environments. The appropriate selection of one or more devices for a particular individual and employment situation is intended to enhance that person's employability, productivity, and job retention.

Methodology—The decision-making processes are being modeled from the processes used by expert rehabilitation specialists in the recommendations of access devices for visually impaired individuals. Experts in the field will incorporate information about the client, job tasks, possible access devices, and available equipment to make the optimal recommendation for that client for that job environment, given agency resources. The CAT:KBES program models this complex process by beginning with a simultaneous consideration of the severity and type of visual impairment of a client and the expected tasks and media requirements of a particular job selected for that client. Other factors which may affect access recommendations, such as a client's tactile sensitivity and hearing ability, are considered next. The model then matches specific devices needed for that client to access the expected media and tasks required for that job. To make these recommendations, CAT:KBES incorporates databases in visual disorders, access technology devices, microcomputers, and job environment and task definitions.

Progress—A national panel of rehabilitation experts have been recruited to advise program developments and the program model is currently being evaluated at three clinical settings.

Results—The multidimensional CAT:KBES model is written in C language under Unix for running on microcomputers with 40 MB hard drives. The CAT:KBES program will be undergoing further testing by rehabilitation engineers in DOE Regions IV and VI early in 1991. Information dissemination for the project is being planned through direct mailings, journals, and conference presentations. The CAT:KBES software will be distributed through Rehabilitation Research and Training Center-sponsored training conferences and technical assistance. System updates are tentatively planned to occur once every 2 to 3 months through use of the Mississippi State University Bulletin Board System for registered subscribers.

[480] Enhancing the Productivity of Randolph-Sheppard Business Enterprise Program Facilities Through Personal Computers

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Sponsor: *National Institute on Disability and Rehabilitation Research; Mississippi State University*

Purpose—The purpose of this project is to produce a directory of personal computers, peripheral hardware, and software resources that could be used by a Business Enterprise Program (BEP) facility operator in the management and operation of a snack bar or cafeteria. The emphasis of the directory will be on the linkage between personal computers and peripheral devices designed for people with visual disabilities, and compatible software which addresses food service industry issues. Specifically, these issues may include: 1) inventory and cost control; 2) financial reporting; and, 3) purchasing and receipts recording. Information to be included in the directory will be: 1) sources/manufacturers of the products; 2) purpose of the product; 3) compatibility of the product; 4) evaluative data; and, 5) estimated costs of the products.

Methodology—To identify software that addresses issues germane to the management and operation of BEP facilities and that is compatible with personal computers and

specialized access devices for blind and visually impaired operators, a literature review of computer application magazines and journals and restaurant trade periodicals will be conducted to identify currently available software. Additionally, food services industry associations will be contacted for their assistance in identifying appropriate software. Manufacturers of food service industry software will be surveyed to obtain information about their products' operating system requirements, operations performed, and documentation available. Manufacturers will also be asked to provide demonstration copies of the software and documentation. Evaluation of the software will focus on user friendliness, compatibility with hardware and access devices accessible to BEP operators, tasks performed, and quality of documentation.

Progress/Results—Work on this project began in October 1990. Results of the project will be published in a directory of food services industry software which identifies:

1) sources of the products or manufacturer; 2) purposes of each product; 3) compatibility of software with acces-

sible computer hardware; 4) evaluative data; and, 5) estimated costs of the products.

[481] Evaluation of Randolph-Sheppard Business Enterprise Program Facility Designs and Effects of Illumination and Color Contrast Considerations

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Sponsor: *National Institute on Disability and Rehabilitation Research; Mississippi State University*

Purpose—The purpose of this project is to identify illumination and color contrast levels that could benefit Business Enterprise Program (BEP) operators in the design or redesign of a variety of facility types in the snack bar and other category. Recommended illumination levels, color contrast and use of color, as well as reflectance levels, will be identified for public areas and work areas, with emphasis on the work areas of the licensed BEP operators with low vision.

Methodology—Recommended illumination levels for facilities of varied size and configuration, as well as common color utilization in such facilities, were determined from literature published by the Illumination Engineering Society of America such as the *IES Lighting Handbook* (Vol. 3), and the Munsell Color Chart. A data collection instrument was developed using the instrumentation

developed for the *Work Environment Visual Demands Protocol*. Data were collected on existing illumination levels and color levels in customer and work areas at 50 BEP facility locations in four states.

Progress—Data from 50 BEP facility locations in four states have been collected. Comparisons are being made with Illumination Engineering Society of America standards and the recommendations for illumination standards given in the *Work Environment Visual Demands Protocol*, an earlier study conducted by the Rehabilitation Research and Training Center on Blindness and Low Vision.

Results—Data analyses and interpretation of results are in progress. A publication of the results of this study will be made available.

[482] Broad-Based Technical Assistance Documents and Agency Effectiveness Analysis to Enhance Competitive Employment of People Who Have Visual Disabilities

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Sponsor: *National Institute on Disability and Rehabilitation Research; Mississippi State University*

Purpose—The purpose of this project is to provide a means for state and private rehabilitation agencies to use a national database to determine answers to agency-specific questions and problems concerning agency policy and service delivery that will benefit management, planning, agency effectiveness, and enhancement of rehabilitation outcomes for people with visual disabilities.

Methodology—During the information synthesis phase, recommendations for procedure, policy and practice

from previous studies of the Rehabilitation Research and Training Center (RRTC) National Blindness and Low Vision Database will be summarized, and questions in the area of management, planning, and agency effectiveness from relevant literature and professionals in the field will be identified. Approaches to answering or addressing these questions using the database will be outlined with examples, and limitations of the database will be noted. The next phase of the project will be to subdivide the database into three sections: client variables, service

variables, and environment and financial variables. Each section of the database will be converted to a PC-compatible relational database format.

Progress—A review and synthesis of the results from previous research on the RRTC's National Blindness and Low Vision Database and a review of current literature relative to management, planning, and effectiveness in vocational rehabilitation agencies is in progress.

Results—The end products will be three volumes containing the variables in the database in a form that can be accessed and manipulated directly by rehabilitation professionals interested in exploring their own questions. The volumes will include summary information on previous research, as well as examples and strategies for using the database.

[483] Workplace Visual Functioning Assessment

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Sponsor: *National Institute on Disability and Rehabilitation Research; Mississippi State University*

Purpose—This project is designed to develop and pilot-test a protocol and kit for the evaluation of the impact of environmental variables on performance in the workplace of persons with low vision.

Methodology—This 2-year project is designed to field-test the *Worksite Assessment Protocol and Kit*. It involves testing of 45 subjects (in two treatment groups and one control group) to assess the impact of intervention on environmental variables in the workplace. The testing protocol involves a clinical assessment for all subjects and then a varied intervention time with the Protocol and Kit. Testing occurs over a 9-month period for subjects

who are provided with intervention at different stages of the project, dependent upon their assignment to the treatment or control group. Variables to be examined include job satisfaction, performance at the job site, and types and nature of environmental modifications.

Progress—A protocol for workplace visual functioning assessment has been developed, reviewed by a panel of experts, and pilot-tested. Field-testing of the protocol is in progress.

Results—Testing will be completed and the protocol reviewed and revised in 1991.

[484] Assessment of the Need for a National Information and Referral Center for Partially Sighted Individuals

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Sponsor: *National Institute on Disability and Rehabilitation Research; Mississippi State University*

Purpose—In this project, research is being conducted to clarify the definitions of low vision; clarify the characteristics of the partially sighted population; clarify the service needs of the partially sighted population; and define and identify services available.

Methodology—A review of relevant literature was conducted to clarify definitions. The review included,

but was not limited to, definitions of low vision and partially sighted status for persons who are and who are not legally blind. Characteristics and service needs of the partially sighted population were investigated through telephone interviews with partially sighted persons, both legally blind and not legally blind. A survey of low vision clinics listed in the American Foundation for the Blind's *Directory of Agencies for Blind and Visually Impaired*

Persons in the United States was conducted to identify and define services available to partially sighted persons. Following initial analysis of data, a prime study group will review the results and make recommendations regarding additional analysis, graphics presentation, and interpretation.

Progress—Data collection is complete and data analyses are in the final stages.

Results—A report of the final results of the project will be submitted to the National Institute on Disability and Rehabilitation Research.

[485] Development of Hemianopsia Glasses

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Sponsor: *The Rehabilitation Centre*

Purpose—The objective of this project was to develop a pair of glasses which simulates what a stroke victim sees with his/her eyes.

Progress/Results—A pair of hemianopsia glasses was made out of ski goggles. The type of goggles used had to

give an excellent peripheric field of view. In addition, the shield had to be as close as possible to the eyes. A separator was attached to the shield to cut the right field of view from the left. Special frosted lenses were fitted to the shield and an adjustment for parallax was provided.

The new glasses are now being evaluated.

[486] Microcomputer Software for Blind and Partially Sighted People

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Sponsor: *Research Centre for the Visually Handicapped*

Purpose—The microcomputer software aspect of the Centre's work is concerned with development of low-cost programs designed to enable visually handicapped people (from pre-schoolers to adults at work) to have access to the same information and facilities as their fully-sighted peers.

Progress—The Centre has a suite of over 40 programs. For very young and less intellectually able children, the materials developed or under development are aimed at the enhancement of various basic perceptual and cognitive skills, with control being effected by means of a conventional keyboard, touch-sensitive screens, joysticks, concept keyboards, and similar devices. For older students and adults, the software (for teaching mathematics and for word-processing purposes) allows for output in the form of large print, Braille, and synthetic speech output from teletext systems.

One particularly interesting set of software allows for "Viewbooks" to be used by partially-sighted students

(*Magnified Viewbooks*) and by totally blind learners (*Talking Viewbooks*). Viewbooks, a commercial product, are books published on disc rather than paper, each page being presented as a "screenful" of information, together with Viewbook commands. These commands help to locate any page, word, or phrase, permit the user to edit or annotate texts that are being studied, and arrange for sections to be produced as hard copy. The texts include classics from English literature, and standard works in Media Studies, Sociology, Geography, Economics, Social Policy, History, and General Studies.

Although the software was originally designed for implementation on the BBC range of microcomputers, much of it is now being rewritten to run on IBM-compatible devices.

Future Plans—With the advice of teachers and rehabilitation professionals, the Centre is extending the range of this low-cost software so that the educational and vocational needs of visually handicapped people can be met.

In addition, more time and resources will be devoted to increasing the range of microcomputers on which the materials can be run.

Recent Publications Resulting from This Research

Assessing Functional Vision Using Microcomputers. Spencer S, Ross M, Br J Spec Educ (Research Supplement) 16(2):68-70, 1989.

Closing the Gap. Facilitating Integration: Microcomputer Technology and the Visually Handicapped Learner. Spencer S, Ross M, Spec Child 28:20-21, 1989.

Software Packages for the Young Visually Handicapped. Spencer S, Ross M, Spec Child 31:20-21, 1989.

Centre Software and Centre Computer Base: Micro-Computers for Blind and Partially Sighted People. Ross M, Spencer S, Tobin MJ, Educare 37:26-28, 1990.

[487] Smith-Kettlewell Rehabilitation Engineering Center

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Sponsor: *The Smith-Kettlewell Eye Research Institute; National Institute on Disability and Rehabilitation Research*

The following are summaries of the past year's projects at the Smith-Kettlewell Rehabilitation Engineering

Center (REC) receiving support from the National Institute on Disability and Rehabilitation Research.

1. Vocational Aids

Progress—The Nattering RAM. Rapid progress was made on the "Nattering RAM" general-purpose stored speech board for use in a wide variety of instruments for the blind. This speech system uses entirely off-the-shelf components, with no specialized synthesizer chips. This approach was taken to avoid the problem of such chips periodically going out of production—resulting in nonavailability of talking instruments for the blind. Prototypes of the device have successfully been made and interfaced with a multimeter, a clock, and a blood pressure gauge. Work is almost complete on the incorporation of the Nattering RAM into the new Smith-Kettlewell "Talk-&Tones Multimeter," a flexible meter which gives both speech and tonal output. (The presence of both types of output is particularly helpful in situations where the signals being measured are changing rapidly.) The Nattering RAM speech board can be user-programmed in any language.

Electronic Music Synthesizers. The accessibility of modern electronic music synthesizers is being studied. We have contacted a number of blind musicians who earn their living in music using electronic equipment. A major reported difficulty is not so much with the use of the computer in arranging the music, but with the mastery of the electronic musical instruments themselves. Without access to the information on the instruments' displays, a blind musician cannot "fiddle" with the instrument in the store to obtain an idea of its features. Some instruments afford further discouragement in the form of a control

panel that is absolutely smooth to the touch. Often, if a blind user becomes disoriented by an erroneous button-push, the only practical solution is to "power down and reboot" the synthesizer, to ensure that such an error will not be stored in the machine's memory. We are exploring possible solutions, including adaptation of a program developed in France to extract more information via the synthesizer's MIDI port.

We are also addressing the problem of accessibility of equipment manuals and testing the suitability of different types of computer access systems for use in conjunction with synthesizer equipment, much of which is intended to be interfaced to computers in order to operate. Ultimately, we plan to produce a handbook to guide the blind musician in the selection and use of modern electronic synthesizers.

Large Print Dymo Embosser. We have had many requests for a large print Dymo Embosser for low vision use. This year we have modified the 3M Scotch™ brand EA200 tape embosser for this purpose. This machine uses three-quarter-inch adhesive-backed plastic tape (similar to Dymo tape) and embosses the tape with one-half-inch high sans serif lettering. Labels made with this machine are very clear and can even be read tactually. However, index markings on the embossing wheel are indistinguishable by touch and are too small to be read by persons with low vision. The common complaint is that, while blind and low vision people can read its output, operation of the machine is inaccessible. We were able to

adapt the machine by adding a large print overlay to the embossing wheel and modifying the internal components so that the right front corner of the tape could be felt as the user positions it for making the next label. The resulting machine appears to be a practical solution for low vision persons wishing to make large Dymo labels.

Fax-Based Reading Service. We explored and demonstrated a Fax-Based Reading Service for the visually impaired. An individual possessing a fax machine could transmit documents (including handwritten ones) to a central location, where a sighted reader could read the document back to him over the telephone. The use of computer-based fax equipment in this application could offer advantages in flexibility and document handling, and would allow a physically handicapped person to perform the function of the sighted reader using one of the systems available to this population for computer access. This year we have implemented a demonstration fax-reading experiment using seven fax machines.

Fax machines come in two types: One type contains an automatic document feeder that can accept loose-leaf documents or single sheets; these do not permit thick materials (e.g., envelopes and pamphlets) to be transmitted. The other type of machine is the so-called "flatbed" type, which affords the greatest flexibility in materials to be transmitted. Resembling copying machines, flatbed fax machines have a glass table on which books, envelopes, magazines, and three-dimensional objects can be placed. The latter type was chosen for the study (Nitsuko). We also obtained a "TurboFax" fax card and software (incorporating most of the desired features) from Imavox Corporation of Santa Clara, interfaced with an IBM/AT-compatible computer with a high-capacity hard drive and EGA graphics capability. This system is being used as the sighted reader station for our study.

Through our initial experiments, we have derived a telephone protocol which is intended to maximize efficiency of the reading process. Examples of test materials successfully transmitted and read in our initial experiments include: preparation instructions for packages of food, gas and electric bills, instructions for computer programs and computer manuals, business cards, "Frequent Flyer" statements and award checks, magazines (pre-identified excerpts), and miscellaneous mail.

A method of transmitting canned goods labels was devised. Thick rubber bands were affixed to each end of the can to act as rubber tires to keep it from sliding on the glass table. The seam of the label was then placed at the lower left, and when the scanning table slowed down (showing that the label was being scanned), the can was

allowed to roll as the table moved to the left. The resultant facsimile was quite readable, since the depth of field of the scanner is approximately 1 cm.

Based on our results, a fax-based reading service for the blind and visually impaired appears technically and practically feasible, and has advantages in cost and flexibility over the provision of automated reading machines. For example, the system can be used to read handwriting, and the sighted reader can make helpful cognitive judgments regarding the reading material (e.g., "advertisement," or "junk mail") which exceed the foreseeable capabilities of any automatic reading machine. Initial user comments indicate that although reading of the materials can be slow, the fact that a fax-based reading service would be available "on call" to the user at any time of the day or week would probably outweigh this disadvantage (which is, in any case, shared by automatic reading machines). In the home environment, for example, blind individuals may have the services of a sighted reader only once a week, compared with the constant accessibility of the fax reading service.

Descriptive Video Services. Two reports were commissioned by the Office of Special Education and Rehabilitative Services regarding "Descriptive Video Services" (DVS, a "service mark" of WGBH). A report on "commercial viability" was done by COSMOS Corporation in Washington, DC, in May 1990, wherein COSMOS studied subjects related to commercial viability. Our companion study and report covered technical questions about how DVS is accomplished, and why it is a more technically viable service now than it would have been before 1984. The report was completed in June 1990 and submitted to OSERS for review by the Congressional Office of Technology Assessment and others, to assist them in determining the future of DVS. Copies of the report are now available from the Smith-Kettlewell Institute.

The SKERF-Pad. The SKERF-Pad is a talking computer access system for the blind which utilizes a touch-sensitive table to represent the computer screen. The user points to any part of the tablet, and the computer reads back the contents of the corresponding point on the screen. This year the system has been modified to allow support for a \$70 "software" speech synthesizer. This product, the "Speech Thing," manufactured by Covox, Inc. of Eugene, OR, is a high-quality speech synthesizer which resides in the memory of an IBM/PC-AT or compatible computer. It requires only a simple adapter and audio amplifier to be connected to the computer's parallel printer port, and in no way interferes with printing. Although this program requires a large amount of

computer memory (106 kilobytes), its low cost and relatively high speech quality make it an attractive alternative to units costing more than twice as much.

Other modifications to the SKERF-Pad screen reader have included the adding of more features to enable easier cursor manipulation, voice changes to indicate screen attributes, and porting to additional synthesizers. Approximately 12 units have been placed in the field for evaluation. A survey of the recipients has been undertaken by an REC student-intern from San Francisco State University. The preliminary results indicate that most users were satisfied with the system and found little difficulty in learning it. The SKERF-Pad is now commercially available.

Tonal and Talking Blood Pressure Meter. A Blood Pressure Meter with both tonal and talking output was

developed in response to requests from visually impaired medical personnel for more accurate blood pressure monitors. A series of tests of the Smith-Kettlewell instrument was undertaken in conjunction with Pacific Presbyterian Medical Center, with positive results.

Talking Traffic Sign. Work was initiated on a collaborative project with the San Francisco Department of Public Works and the San Francisco Lighthouse to install a Talking Sign demonstration system on Market Street. Discussions are ongoing with Econolite, Inc. (the largest U.S. manufacturer of traffic signals) and U.S. West (a Bell Telephone Company) regarding possible expanded installations.

Auditory Oscilloscope/Auditory VU-Meter. The Smith-Kettlewell Auditory Oscilloscope and Auditory VU-Meter became commercially available this year. The manufacturer is Oehm Electronics of Hayward, CA.

2. Educational and Multihandicapped Aids

Progress—Flexi-Formboard. The Smith-Kettlewell Flexi-Formboard reached the status of commercial availability this year. The device is produced by Adaptive Communications System of Clinton, PA.

Jumbo Key Caps. New approaches for educational aids for the visually and multiply impaired child are underway. One example is "Jumbo Key Caps," a new concept for a low-cost approach to the use of computers as learning tools for the visually impaired.

Dexter Finger-Spelling Hand. The Dexter system, a robotic finger-spelling hand for the deaf blind, was transferred to a commercial company, Upstart Robots, Inc.,

with a view to eventual commercial production. An improved prototype was developed and demonstrated at the 1990 RESNA Conference, and further refinements are underway.

TeleBraille. A new TeleBraille, a braille-output telephone communication device for the deaf-blind, was developed this year. This project is being carried out in collaboration with Telesensory Systems, Inc., who will undertake commercial production upon completion. A working prototype has been demonstrated, and initial field testing is about to begin. Production is scheduled for early 1991.

3. Low Vision Projects

Progress—Low Vision Illumination Aids. Our prototype low vision illumination aids began the evaluation phase, and have excited considerable interest from low vision clinics around the country. A simple telescope handle modification developed by the REC (making it possible to hold and focus the telescope with one hand) is evoking similar interest. Work on these and other low vision projects has been carried out in conjunction with PPMC Low Vision Services.

Low Vision Reading Study. Our Low Vision Reading Study was completed this year, with favorable results. The study showed that, contrary to earlier findings by others, it is beneficial to utilize a "viewing window" of more than four characters when reading. This result

will be important in its effect on the design of low vision aids.

Visual Function While Driving. Funding was obtained from the California Department of Motor Vehicles to explore the correlation between driving problems and different measures of visual function (particularly new experimental vision tests developed at Smith-Kettlewell). To date, 90 subjects have been run in this study, which is also being used as a testing ground for the new Smith-Kettlewell Low Vision Tests.

Functional Low Vision Tests. New functional low vision tests under development include the SKILL chart (Smith-Kettlewell Institute Low Luminance), variations on the Amsler Grid, and the Retinal Rate of Recovery

test. Methods for low-cost production of the SKILL Chart have been explored, and success has been achieved with a photographic method which should result in a projected production cost of less than \$5 per chart (compared with up to \$300 for presently available low-contrast charts).

Early Detection of Age-Related Maculopathy. A new color test was developed for the early detection of age-related maculopathy. The test utilizes an adjustable diaphragm to allow estimation of central versus peripheral color sensitivity.

A series of modified images were produced to simulate, more realistically than previously possible, the effects of early macular disease on visual function. Typical driving scenes were modified by defocusing, color wash-out, etc., to approximate the reports of actual patients. It is hoped that these images will help increase understanding of the functional handicapping effects of macular disease, particularly in its early stages, which have received little attention.

[488] Pictures for Persons Who are Blind: A Study with Raised Line Drawings

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Sponsor: *Center for Therapeutic Applications of Technology*

Purpose—Until very recently there has been little in the way of pictures for persons who are blind. Children's books at best provided only textual information about the pictures. Secondary and postsecondary education textbooks were rarely designed to provide accommodation for the graphs, charts, and illustrations that sighted students take for granted.

Technology now exists to make raised line drawings at a relatively low cost. Using a scanner, virtually any picture or graphic can be scanned into a computer file, and saved in a format that can then be forwarded to a printer that produces a raised line drawing.

The purpose of this study is to explore the parameters for successful use of raised line drawing technology by persons who are blind. The first phase of this study will explore mental images of items in the environment of persons who are blind.

Methodology—Thirty subjects are participating in this study. For six common objects, each subject is asked to describe the objects, then is presented with a raised line drawing of the object. The subject is asked if there is anything on the raised line drawing that he/she was not aware of prior to this exercise.

Project hardware includes the Arkenstone Reader, marketed by Arkenstone, Inc., an optical character recognition device that scans printed material directly to binary computer storage. The Pixel Master, by Howtek Corp., is a print output device that generates multi-color raised line images. Subjects explore the raised line images with the NOMAD, marketed by Quantum Technologies, which provides a touch-sensitive grid pad that interfaces with a voice-synthesizer computer to provide voice output in response to pressure on the pad. The output from each point on the pad can be programmed in relation to the image overlain on the pad.

Progress—We have found that there are many details in the environment that blind persons discover when presented with a raised line drawing. Their mental images of objects often lack detail.

Future Plans—Future work will include studies directed at determining the optimal format for raised line drawings for ease of use and maximizing learning. One important parameter for pictures is a mechanism for conveying "feelings"—the emotions evoked by experiencing an image. Use of heavier lines, alternate textures or other mechanisms will be explored.

[489] Fast Motion in Unknown Environments with NavBelt: A Sophisticated Electronic Travel Aid for the Blind

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Sponsor: University of Michigan

Purpose—The development of a sophisticated computerized Electronic Travel Aid (ETA) for blind and visually impaired individuals has begun at the University of Michigan. The device will consist of a belt with a small computer, ultrasonic and other sensors, and support electronics. Signals from these sensors will be processed by a unique algorithm and relayed to the user via headphones. This device, called *NavBelt*, will enable a blind user to quickly and safely walk through unknown, obstacle-cluttered environments.

Progress—The NavBelt system will provide binaural feedback (acoustic stereo signals which create the impression of sound coming from different directions) in two distinct modes of operation: the *guidance mode*, and the *image mode*.

The guidance mode is a novel ETA concept for fast, safe travel. In this mode, either the direction of travel or the target location is known to the system. A single binaural signal actively guides the user around obstacles in pursuit of the target direction. Preliminary experiments show that only a minimum of conscious effort is required by the user to follow this directional signal. In the guidance mode, two special features let the system automatically determine the direction of travel: 1) the contour-following feature guides the user alongside walls, sidewalks, etc.; and, 2) the averaging feature monitors a sequence of the user's steps (when invoked) and then determines a direction by extrapolation. Obstacle avoidance and active guidance are maintained with both features.

The image mode will present the user with an acoustic image (a 180-degree panorama) of the environment. Advanced statistical signal-processing algorithms compensate for sensor inaccuracies and provide the user with a more accurate and intuitive image than do existing ETAs.

The underlying technology of the NavBelt is based on our previously developed Obstacle Avoidance System (OAS) for mobile robots—a proven and mature technology considered by many experts to be the best mobile robot OAS in the nation.

The main advantages of the proposed NavBelt over existing ETAs are: 1) the NavBelt not only detects obstacles but actively guides the user around the obstacle; 2) the NavBelt can guide the user in a predefined direction or toward a predefined target—both while actively guiding the user around an obstacle; 3) the NavBelt can automatically guide the user alongside walls; 4) the NavBelt does not require active scanning by the user (as is the case with hand-held devices). It automatically scans a horizontal sector of 120 degrees in front of the user and protects the user vertically “from head to toe”; 5) the NavBelt can provide the user with a 120-degree panorama of the environment (when operating in the image mode); and, 6) the NavBelt provides the user with full protection and serves as the primary travel aid. The long cane is used as a secondary device (e.g., after the NavBelt detects a step, to measure the size of the step).

Results—We have demonstrated the feasibility of the proposed system in an experiment in which a blindfolded user is seated on top of a vehicle. The vehicle is equipped with an OAS, similar in principle to the one proposed here. Relying on the signals generated by the OAS, the user steers himself and the vehicle through an unknown, obstacle-cluttered environment.

Recent Publications Resulting from This Research

The NavBelt—A Computerized Multi-Sensor Travel Aid for Active Guidance of the Blind. Borenstein J, Koren Y, CSUN's Fifth Annual Conference on Technology and Persons with Disabilities, Los Angeles, 1990.

D. Deaf-Blind

[490] A Second Generation Mechanical Hand Communication Aid for the Deaf-Blind

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—A solution to communication problems that deaf-blind people experience is offered by "Dexter II," a second-generation computer-based electromechanical fingerspelling hand. This device enables a deaf-blind user to receive tactile messages from the mechanical hand in response to keyboard input during person-to-person communication, as well as to gain access to computer-based information.

Progress/Methodology—This work is an outgrowth of a 1985 project in which four graduate Stanford mechanical engineering students designed and fabricated a mechanical fingerspelling hand. A major goal at that time was to develop a system with easily modifiable finger positions. This quality was realized in the completed project, a new robotic fingerspelling hand named "Dexter."

A more compact version of the original Dexter mechanical system was designed in Spring 1988 by three graduate mechanical engineering students. Their design, Dexter II, employs DC servo motors to pull the finger drive cables of a redesigned hand, thereby eliminating the need for the pneumatic power source. A speed of approximately four letters per second (almost twice that of the first design) can be achieved with the improved device.

In operation, a message is typed on a keyboard (an Epson HX-20) by an able-bodied person. The ASCII value of each letter is used by the software as a pointer into an array of stored control values. This data programs pulse-width modulation chips which operate the eight DC servo motors in Dexter II. These motors then pull on the drive cables which are the "tendons" of the fingers, producing finger flexion. The hand configuration is felt by the deaf-blind communicator and interpreted as letters of a message.

Although neither Dexter nor Dexter II can exactly mimic the human hand in fingerspelling all the letters, they can display close approximations that are easy to learn by the deaf-blind user.

Results—Deaf-blind clients of Lions Blind Center (Oakland, CA) served as subjects for the initial testing of Dexter. They were able to identify most of the letters presented by the robotic hand without any instructions, and in less than an hour were correctly interpreting sentences. Equally important was their positive emotional reaction to the hand. They seemed to really enjoy using it, and were intrigued by its novelty. There were no negative comments made concerning its mechanical nature or any other aspect of the system.

Dexter II was first tested by a deaf-blind person who is extremely proficient at receiving tactile fingerspelling. She provided many suggestions for improving the letter-shape configurations of Dexter II. Later, it was introduced to 12 deaf-blind people during an annual retreat. About 20 deaf-blind attendees at the annual Deaf-Blind Conference in Colorado Springs in June 1989 had a chance to experience Dexter II. The device was also exhibited at the RESNA '89 Conference in New Orleans, and at the InvenTech meeting in Anaheim in September 1989. The ability of deaf-blind individuals to initially understand Dexter II varied considerably.

Future Plans/Implications—Dexter is intended to serve deaf-blind users as a complete receptive communication system, not just a means of receiving information in face-to-face situations. Its ability to respond to computer input means it can be interfaced to a TDD to provide deaf-blind people with telephone communication. It can also be connected to computers to provide expanded vocational and avocational opportunities for the deaf-blind community.

A Request for Evaluation is being written and will be submitted to the Rehabilitation Evaluation Unit to obtain funds for the manufacture and evaluation of commercial prototype units.

Recent Publications Resulting from This Research

Dexter—A Finger-Spelling Hand. Jaffe DL, OnCenter—Tech Trans News 1(1), 1989.

[491] A Robotic Fingerspelling Hand for Communication and Access to Text by Deaf-Blind Persons

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This 3-year project is intended to define and assist in the development of a robotic fingerspelling hand, and to evaluate the utility of and consumer reaction to this type of device. A proof-of-concept prototype was available at the outset of the project, and we were able to demonstrate the concept to deaf-blind people (who can only receive a demonstration via tactile means, in that videotape is inaccessible to them).

Progress—Deaf-blind consumers and interpreters were involved in the development of a thorough functional specification for such a device. The specification was circulated to experts in the field and revised; it is now being used as a basis for evaluation of the hand.

The concept for the design involved the use of bio-metal for the actuation of muscles in the hand. During the first year and a half of the project, components were evaluated and a hand assembled for evaluation.

Methodology—The evaluation involves measurement of certain characteristics of the hand (e.g., amount of noise

generated by the device, weight, dimensions, cost of components, etc.) and observation of the hand's performance when fingerspelling (clarity, consistency, speed, etc.). Specific design weaknesses that appear to affect fingerspelling performance will be documented. User evaluation will be included, with approximately 12 deaf-blind people serving as informants on this task. Baseline measures of receptive fingerspelling speed using human hands will be collected. Users will evaluate the intelligibility of fingerspelling, acceptability of the hand with regard to size, acceptability of various positions in which the hand can be used, acceptability with regard to any vibration present in the hand, etc.).

Future Plans—Our initial observations indicate that the hand appears too arthritic to perform fingerspelling, and the speed of spelling is quite slow. Future direction for the project will now be determined.

[492] Application of Technological Devices for the Enhancement of Cognitive Performance and Communication in Prelingual Deaf-Blind Children

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Purpose—The primary purpose of this 36-month project was to demonstrate specific procedures for meeting the complex communication needs of prelingual, profoundly deaf-blind children via the development of intervention tools/techniques, and the adaptation or development of technological assistive devices.

Progress—Technical devices developed to date encompass four areas: signaling devices, cognitive toys, exercise motivational aids, and assessment tools.

Appropriate signaling systems would allow the child to request and make appropriate responses to the requests

of others. The signaling devices are viewed as a means to the eventual initiation of more complex cognitive and communicative behaviors by the deaf-blind child allowing the child to exercise some degree of control and to grow in self-esteem and awareness of the near and distant environment. Since the project's inception in September 1987, several commercial signaling systems have been purchased, tried, and modified to meet the needs of this population. They include the Tacticon 1600, Tactaid II, Voice-Lite, and Mini-Fonator. The latter has undergone a third adaptation effort (a wireless microphone link) in order to eliminate extraneous wires

and to limit pick-up of ambient noise and extraneous vibrations.

A toy based on a commercially available "Simon" has been designed and built. This Multi-Sensory Simon (MSS) produces strong tactile vibrations in addition to bright light and sound outputs. The MSS flashes and vibrates with increasingly lengthier patterns of vibrations at its four distinctly-shaped and colored translucent control buttons. When a child is able to replicate this pattern by depressing the corresponding panels, a tactile-plus-auditory reward is given. To assess the tactile sensitivity of deaf-blind children, a series of tubular-shaped batons were made using materials having a wide range of tactile characteristics (e.g., woolen felt, corrugated cardboard, smooth and rough plastic, wool and outdoor carpet, wooden dowels, etc.). Other multisensory and motivational toys (fan, radio, and a musical bear) have been purchased for use in various intervention strategies.

Technological devices were also developed to promote physical fitness in deaf-blind children, including an adapted trampoline to encourage an exercise and communicative dyad. To motivate exploratory behavior in an upright position, a child's walker and a push toy were instrumented to produce music when the desired direction, distance, and rate of travel occurred. A custom-built electronic box that imitated the sound of a motorcycle was added to a exercise bicycle. By producing sounds that varied in response to the rate of pedaling, this instru-

mented bicycle has strongly motivated a deaf-blind child to exercise regularly and enthusiastically.

As an aid for teaching proper sequencing and task completion concepts, several portable table tops of various sizes have been made to interface with an assortment of switches. These switches (self-timed, latched, and/or simultaneously activated) can be used to provide rewards of music and vibrations upon proper sequencing of tasks.

Other project activities include a summer swimming and gymnastic program designed to facilitate independent mobility and enhance communication in highly motivational non-classroom types of setting. Two clients in 1988 and four in 1989 have participated in this program. Their progress in achieving improved mobility and communication skills has been very encouraging.

Future Plans—Remaining tasks include the preparation and dissemination of brochures, videotapes, and manuals that describe the project's findings.

Recent Publications Resulting from This Research

Characteristics and Usage of Audible Pedestrian Traffic Signals.

Szeto AYJ, Valerio N, in Proceedings of the 5th Annual Conference on Technology and Persons with Disabilities, Los Angeles, 665-682, 1990.

A Piagetian Model for Observation of Verbal, Nonvocal, and Nonverbal Cognitive Behavior, in Cognition, Education and Deafness—Vol. II. Christensen KM, Washington, DC: Gallaudet University Press, 1990.

[493] Validation of Instructional Practices with Youth Who Are Deaf-Blind

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Sponsor: Office of Special Education Programs, U.S. Department of Education; Mississippi State University

Purpose—The purpose of this study is to identify modifications in instructional practices that are necessary for use with deaf-blind students by observing changes in teacher-student interactions.

Methodology—The method will involve a time-series design incorporated into case studies. This project will involve rating communications between teacher and student, pre- and post-tests of teacher job satisfactions, ratings of teacher self-efficacy before and after intervention, and teacher design, and use of specific adaptations in instructional strategies in order to teach a deaf-blind student.

Progress—Published instruments have been selected for pre- and post-measures. Instruments have been designed to collect demographics, teacher self-efficacy ratings, and to record observations of teacher-student communication. Ten research sites have been selected. The intervention has been designed and scheduled. Data collection has been scheduled.

Results—This project is in the data collection phase; no results are available to date.

[494] Improving and Expanding Social Interaction Skills of Youth with Deaf-Blindness in Supported Employment Settings

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Sponsor: Office of Special Education Programs, U.S. Department of Education; Perkins School for the Blind; Mississippi State University

Purpose—The purpose of this study is to categorize the kinds of interventions that are designed by an expert team to facilitate the work adjustment of deaf-blind students.

Methodology—The method will involve a time-series design incorporated into case studies. Each student will have an “expert team” comprised of teacher, job coach, etc., who will observe typical examples of the student’s situation at work. The team will design any necessary interventions. A thematic analysis will determine whether

there are common modifications made across students and whether most modifications are made regarding the student’s behavior, or accommodations in the work place.

Progress—Instruments have been developed to rate videotaped behavior of deaf-blind students in a vocational setting.

Results—No results are available to date; the project will end in September 1992.

XV. Spinal Cord Injury

For additional information on topics related to this category see the following Progress Reports: [86], [102], [112], [113], [114], [117], [118], [144], [145], [148], [149], [150], [169], [182], [185], [194], [230], [322], [323], [378], [384], [399], [400], [401], [403], [413], [414], [574], [578], [595], [596], [608], [609], [611], [612].

A. General

[495] Accelerometric Body Segment Motion Analysis During Spinal Injury Patient Handling: A Pilot Study

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Purpose—To meet the need for more precise methods of quantifying the dynamic performance of devices for immobilizing, moving, and maintaining traction on cervical spinal cord injury (SCI) patients, we developed a method for measuring relative head-to-trunk motion using accelerometers. We tested installation and simulated patient handling of 8 types of backboards and cervical collars using 14 able-bodied subjects. Alignment and traction stability on the kinetic bed were measured with seven able-bodied and two acute SCI patients.

Methodology—Measurements were made using 3-axis ± 5 G silicon accelerometers on the front and right side of the head and chest. A 50-lb range cable tension transducer indicated traction force. Signals were amplified, digitized, and stored by an IBM PC-XT.

In order to test the ability of the lateral supports of the kinetic bed to maintain spinal alignment and the constancy of traction force, we measured relative head-to-body acceleration during placement and rotation of able-bodied postacute and acute SCI subjects on the kinetic bed. We also measured traction force versus rotation angle of three different traction devices (the sheathed steel cable normally supplied with the kinetic bed, a 9-spring constant-force traction unit, and a cord on a swiveling pulley). Continuation of cervical collar installation and function consisted of testing of the Olympic Medical "Vac-Pac" conformable splint.

Results—Evaluated prehospital support devices include: the traction, alignment, cervical immobilization, and transport (TACIT) device (a short spine board with width-adjustable foam-padded shells for applying non-invasive traction); the Miller backboard; the Dixie backboard; and the Rehabilitation Research and Development Center's composite backboard.

Three types of rigid cervical collars (Philadelphia, Malibu, and StifNeck) were evaluated using normal volunteers. Manual and automatic operation of the RotoRest kinetic bed, as well as lifting onto this bed, were tested at the Santa Clara Valley Medical Center, using normal volunteers and post-acute SCI patients.

Traction force versus rotation angle without complications due to movement of a patient on the bed showed that force output for the sheathed cable varied four times as much as the constant-force unit. With able-bodied subjects, the sheathed-cable method ranged from 3.15 to 4.3 lbs and the constant-force unit produced 2.6 to 2.85 lbs during a rotation cycle, confirming published observations of variation with angular position. Traction force for one SCI patient ranged from 4.4 to 13.5 lb; the other varied from 6 to 14.5 lb. Torsional head-to-body motion between the sensor sites totaled 2.9 degrees in both the able-bodied and SCI subjects during a complete rotation cycle.

Data for backboards and collars were examined to identify activities associated with higher-than-background risk of unintentional neck displacement, including:

closure of fasteners during installation; head elevation while installing posterior components of collars; ineffectiveness of a collar's occipital restraint in extension; jostling as the attendant's hands grasp a backboard; contact of backboard edges with floor for log-rolling; slipping of the subject's trunk, or less frequently leg, if straps were not adequately tightened; and, progressive loosening of Velcro head-restraint attachments. Such findings may be useful to equipment designers attempting to minimize motion, and they may coincide with avoidable neck pain in patients.

Future Plans—Testing of traction force on the RotoRest bed confirmed published observations of variation with angular position; changes in traction force and relative head-body torsion angle were demonstrable during routine activities such as suctioning a tracheotomy tube

and shifting a patient lower on the bed. The possibility of improving spinal stability on beds and similar equipment has led to discussions of future collaboration with potential local manufacturers of traction devices and with the manufacturer of the RotoRest bed (Kinetic Concepts, San Antonio, TX). A proposal has also been submitted to NASA for testing of spinal stabilization during helicopter aeromedical transportation.

Recent Publications Resulting from This Research

Effectiveness of Cervical Spine Stabilization Devices: Accelerometric Identification of Risk Factors During Installation and Use. Sabelman EE, Sumchai AP, Martino JM, in Proceedings of the 12th Annual RESNA Conference, New Orleans, 125-126, 1989.

Dynamic Traction Force and Neck Stability on the Kinetic Bed. Sabelman EE et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 175-176, 1990.

[496] Factors Influencing Joint Compliance and Reflex Mechanisms Following Spinal Cord Injury

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Sponsor: VA Rehabilitation Research and Development Service (Project #B446-RA)

Purpose—Electrical stimulation of muscle has been proposed as a technique to restore function to paralyzed muscles. But, from a control standpoint, little is known about how such artificial activation interacts with the still intact spinal reflex loops. We have developed instrumentation to measure and compare ankle compliance and muscle electromyographic (EMG) activity when the ankle is subjected to perturbations in torque or angular position from bias positions that are achieved volitionally or via electrical muscle stimulation. We also use this instrumentation to quantify the effect of anti-spasmodic pharmaceuticals, since objective measures of spasticity are hard to obtain clinically.

Methodology—We have developed instrumentation and analytical techniques that we use for quantitative measurements of joint compliance in individuals with spinal cord injury and in the neurologically intact. Essentially, the instrumentation consists of a high-powered torque motor that rotates the joint under test over a few degrees, with the resultant torque, position, and acceleration

changes measured. Joint compliance is the incremental relationship between angular displacement and torque, after the effects of acceleration are excluded, and is the inverse of joint stiffness.

We deliver precise torque or position perturbations (step, ramp, sinusoidal, random) to the ankle via a pivoting footplate driven by a computer-controlled torque motor. Angular displacement, torque, acceleration, and two to four channels of EMG data are collected on analog (VHS) tape and simultaneously digitized and stored. Torque or position biases away from normal ankle equilibrium position are applied volitionally (for the neurologically intact or impaired) or via electrical stimulation of the gastroc/soleus or the tibialis anterior muscle (for either the neurologically intact, impaired, or paralyzed). A special stimulator/recording amplifier permits the recording of EMG signals from the muscle being stimulated. An overview of the features and response characteristics of the perturbation system and a comparison from preliminary studies of responses at different biases achieved volitionally versus those achieved by

stimulation are listed in Recent Publications Resulting from This Research.

Results—In the last 6 months, we have studied 17 individuals, approximately half with spinal cord injury. We found that in general the mechanical response of the ankle is quite different under the two types of bias. The joint is far less compliant under volitional bias than under stimulated bias. This is possibly due to subjects with volitional control co-activating the soleus and tibialis anterior. The EMG response shows differences in the evoked stretch reflex. Under volitional bias there was very little, if any, evoked response in the tibialis anterior when the ankle was plantarflexed, while there was significant response in the stimulated bias condition.

In the relaxed state, preliminary results indicate that the ankle stiffness of neurologically intact individuals falls within a much narrower range than that obtained from those with spinal cord injury. We are currently analyzing these data to see if the variability seen in the spinal cord injured population can be attributed to factors like time-since-injury, complete-

ness of injury, extent of antispasmodics prescribed, and other variables.

Future Plans—We are now extending these observations to the knee, because control of the knee plays a much more important role in the ultimate functional use of electrical muscle stimulation than was previously thought.

Recent Publications Resulting from This Research

Biomechanical Responses to Ankle Perturbations During Electrical Stimulation of Muscle. Robinson CJ et al., in *Advances in External Control of Human Extremities*, D.B. Popovic (Ed.), 10:145-158, 1990.

A Comparison in Neurologically Intact and Spinal Cord Injured of Ankle Joint Compliance and Reflex Activity to Angular Perturbations Using Volitional and Electrically Stimulated Biases (Abstract). Flaherty B et al., in *Proceedings of the Annual Meeting of the Society for Neuroscience*, 16:1316, 1990.

Reflex Responses to Ankle Perturbations During Electrical Stimulation of Muscle. Robinson CJ et al., in *Proceedings of the Rocky Mountain Bioengineering Symposium*, Denver, 1990.

Responses to Ankle Perturbations During Electrical Stimulation of Muscle: Interaction Between Ankle Compliance and Timing of Stimulation. Robinson CJ et al., in *Proceedings of the Annual International Conference of the IEEE/Engineering in Medicine and Biology Society*, 11, 1990.

[497] The Corticospinal System

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Sponsor: VA Rehabilitation Research and Development Service (Project #B389-2RA)

Purpose—The purpose of our studies is to identify corticospinal systems which may be important in the recovery of motor function following spinal cord or cortical injuries. Our current studies focus on the corticospinal projections from the primary motor cortex and the premotor areas in the frontal lobe. Classically, the premotor cortex has been viewed as functionally distinct from the primary motor cortex and as a center for the integration of complex skilled movements. Premotor cortex was thought to participate in the generation and control of distal movement only through its projections to the primary motor cortex (area 4). On the other hand, there is a remarkable recovery of motor function that follows lesions of the primary motor cortex. Several studies have suggested that this recovery may depend on the integrity of output pathways from the premotor cortex. We have proposed that the premotor areas contribute to the corticospinal system and, as a result, have output pathways

which are independent of the primary motor cortex. The goal of our experiments is to define the organization of descending projections from the premotor areas and then compare this organization with that of projections from the primary motor cortex.

Methodology—We have examined the topographic organization of corticospinal projections to cervical segments of the spinal cord. In macaques, one fluorescent tracer was injected into upper cervical segments (C2-4) of the spinal cord. Then, in the same animals, a second fluorescent tracer was injected into lower cervical segments (C7-T1). Retrograde transport of these tracers was used to define the origin of corticospinal projections to each segmental level.

Results—Previously, we demonstrated that a substantial portion of the corticospinal system from the frontal lobe

originates from six premotor areas, as well as from the primary motor cortex. Our present experiments indicate that five of the six premotor areas have corticospinal projections to both upper and lower segments of cervical spinal cord. Most of the corticospinal neurons in these areas terminated selectively in either upper or lower cervical segments; only 5% of the sample sent branches to both levels. Only the arcuate premotor area, which is located on the caudal bank of the arcuate sulcus, had a segmental termination that was limited almost entirely to upper cervical segments. These observations suggest that lesions of the spinal cord which selectively affect lower cervical segments would leave a large system of corticospinal projections to upper cervical segments intact.

In the premotor areas, as well as in the primary motor cortex, regions which project to upper cervical segments overlapped those which project to lower cervical segments. However, in each cortical area, the peak densities of corticospinal neurons projecting to the different segmental levels were spatially separate. These results suggest that the topographic organization of arm representation in five of the six premotor areas is similar to that in the primary motor cortex.

The maps of arm representation generated by our studies differ from the classical maps of Woolsey et al. (1952) in at least two striking respects. We found two "lower cervical only" bands of corticospinal neurons in the region of primary motor cortex where Woolsey's map located a single arm representation. Furthermore, we found dense corticospinal projections to lower cervical segments in the region of the supplementary motor area (SMA) where Woolsey's map located the leg representation. These observations suggest that the maps of body representation in the primary motor cortex and the SMA should be reevaluated.

Recent Publications Resulting from This Research

Corticospinal Projections from the Motor Areas in the Frontal Lobe. Dum RP, Strick PL, in Taniguchi Symposia on Brain Sciences No. 12: Neural Programming, 49-63, M. Ito (Ed.). Tokyo: Japan Scientific Societies Press, 1989.

Premotor Areas on the Medial Wall of the Hemisphere: Corticospinal Projections to the Cervical and Lumbosacral Cord. He SQ, Dum RP, Strick PL, Soc Neurosci Abstr 15:282, 1989.

Premotor Areas: Nodal Points for Parallel Efferent Systems Involved in the Central Control of Movement. Dum RP, Strick PL, in Proceedings of the Dahlem Workshop on Motor Control: Concepts and Issues (in press).

[498] Colorado Comprehensive Spinal Cord Injury Surveillance Program

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Sponsor: *Colorado Department of Health; Rocky Mountain Regional Spinal Injury System; National Institute on Disability and Rehabilitation Research; Centers for Disease Control*

Purpose—The Early Notification System (ENS) conducts comprehensive, population-based spinal cord injury surveillance, assesses changing trends in injury demographics, etiologies and outcomes, and identifies risk factors, enabling the implementation of primary and secondary prevention efforts. This particular program is conducted in collaboration with the Colorado Department of Health and is funded both by the National Institute on Disability and Rehabilitation Research and by a cooperative agreement from the Centers for Disease Control for the prevention of disabilities. Its purpose is the identification and development of strategies of prevention and control of secondary disabilities of spinal cord injury.

Methodology—The collection of ongoing secondary disability, medical complications, and cost surveillance data

will be added to existing surveillance information. In addition, tools that measure physical and societal functioning will be used in annual patient interviews. During 1991, a one-time study of ongoing care costs among a sample of 60 clients will be conducted. Established cost determination methodologies will be used, which identify all providers of medical services (including physicians, hospitals, clinics, pharmacies, equipment vendors, attendants, etc.) over a 1-year period. Detailed billing for those services to clients in the sample will be obtained.

Progress—Over 400 patients have been identified since January 1, 1986, and continue to be tracked.

Future Plans—Medical complication and secondary disability data will be analyzed, and preventable conditions amenable to intervention will be identified. Cost data will

also be analyzed to document the costs of ongoing SCI care, the total cost of spinal cord injury in Colorado, the proportion of SCI expenditures attributable to preventable

secondary complications and disabilities, and the economic impact of primary and secondary prevention. Appropriate interventions will be designed.

[499] Psychosocial Adjustment of Persons with Combined Spinal Cord Injury and Traumatic Brain Injury: A Longitudinal Investigation

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Spinal cord injury (SCI) is often the result of a rapid deceleration event and/or a direct impact to the head, neck, or trunk. Therefore, in some cases, an associated traumatic brain injury (TBI) is sustained in addition to the SCI. While evidence of a concomitant traumatic brain injury is at times quite apparent, at other times, “softer” signs of a TBI may not be so apparent and may be overlooked. This project is an attempt to determine whether persons with concomitant TBI in addition to SCI: 1) experience more marital/familial distress post-discharge than a matched group of patients with SCI only; 2) achieve less progress educationally and/or vocationally post-discharge than a matched group of patients with SCI only; 3) experience more psychological/behavioral distress post-discharge than a matched group of patients with SCI only; and, 4) experience more social maladjustment post-discharge than a matched group of patients with SCI only.

Methodology—The social, vocational, psychological, and familial adjustment over time, of a cohort of persons

with SCI and concomitant TBI, and a matched control group of persons with SCI only, have been compared through a battery of well-validated psychometric measures administered via mail.

Results—This study has now been completed. We found that most of the head injuries we identified in this population were mild or moderate and had no important prognostic impact on long-term adjustment. There was a relationship, however, between the more severe injuries and long-term adjustment.

Recent Publications Resulting from This Research

Spinal Cord Injury and Traumatic Brain Injury: Results of a Controlled Follow-up Study. Richards JS, Jaworski TA, Reeder K, ASIA Abstracts Digest 15, 18, 1989.

Spinal Cord Injury and Traumatic Brain Injury: Results of a Controlled Follow-up Study. Richards JS, Jaworski TA, Reeder K, Paraplegia (in press).

[500] A Longitudinal and Cross-Sectional Analysis of Well-Being in Persons with Spinal Cord Injury and Their Caregivers

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Recent clinical and empirical studies suggest there may be an increasing toll in terms of coping and feelings of well-being for persons who live with spinal cord injury (SCI) for 10, 20, and 30 years. Moreover, this toll is more quickly taken when the initial injury occurs at a more advanced chronological age. This study will examine the quality of life of both the person with SCI and his/her caregiver at several intervals postinjury. We

propose to study the patient/caregiver interaction both cross-sectionally and longitudinally to determine whether changes in well-being occur over time, and if so, what factors account for that change, and whether the same factors affect changes in well-being at different times postinjury. The project is an attempt to: 1) examine the relationships between factors of well-being in persons with SCI and their caregivers measured at preselected

times postinjury; 2) determine the association between physical and psychosocial characteristics of the person with SCI and the feelings-of-burden variables in caregiver(s) at preselected times postinjury; 3) determine the interrelationships between feelings of well-being of the person with SCI and his caregiver(s) in different cohorts over time; and, 4) determine the interrelationships between physical and psychosocial characteristics of the person with SCI and feelings-of-burden in the caregiver(s) over time.

Methodology—Persons with SCI and their caregivers will be studied during the short-term (1-2 years), mid-term (4-7 years), and long term (9-13 years) postinjury periods. Yoked SCI/caregiver pairs, both of whom agree

to participate, will be included in the study. We will include 80-120 pairs for each of these three cohorts. Data will be collected representing four hypothesized constructs. The first two constructs will be caregiver and patient well-being, which will be assessed by collecting data on the physical health, mental health, finances, and social activities of both the patient and caregiver. The third construct will be the caregiver's feelings-of-burden, which will likely be composed of measures of social support, the Zarit scale, the Robinson Caregiver Strain Index, the short form of the Beck Depression Inventory, and the State-Trait Inventory. The fourth construct will be patient status, including measures of functional independence, psychosocial status, incidence and prevalence of medical complications, and perceptions of pain.

[501] Long-Term Costs of Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this study is to: 1) develop predictive models to estimate lifetime expenditures for individuals who have spinal cord injuries; 2) estimate the effect of spinal cord injuries on the earning potential of these persons; 3) estimate the aggregate costs of spinal cord injury to society; and, 4) estimate the proportion of lifetime services provided by NIDRR-sponsored model spinal cord injury care systems.

Methodology—A random sample of 651 patients injured 1 to 16 years ago was selected from the National Spinal Cord Injury Statistical Center (NSCISC) database. An additional 300 newly injured patients were also randomly selected for inclusion in the study at the time of admission to any of the 13 currently funded model systems. For each study subject, data are being collected prospectively using standardized forms and instructions on all charges incurred and wages earned during the next one year period. All information required for submission to the NSCISC database is also being collected at this time.

Multiple linear regressions analysis will be used to develop predictive models for annual expenditures, with first-year costs being analyzed separately from those sub-

sequent years. When possible, cost categories (hospital charges, physician fees, attendant care, medications, supplies, etc.) will also be analyzed separately. These annual cost estimates combined with projections of life expectancies developed from our previous research will result in estimates of lifetime direct costs of care.

Indirect costs will be estimated using the human capital approach by comparing wages before and after spinal cord injury, and previously reported estimates of the incidence of spinal cord injury will be used to assess the aggregate costs to society. Sensitivity analysis will be conducted to assess the effects of the models' underlying assumptions. Finally, an assessment will be made of the proportion of services provided by the system of care and the proportion of services provided elsewhere.

Preliminary Results—Patient enrollment is complete and data collection is ongoing. Preliminary analyses of data have not been conducted at this time.

Future Plans—Data collection terminated September 30, 1990, and data analysis is scheduled for completion by September 30, 1991.

[502] Aging in Relation to Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Under the auspices of the Rehabilitation Research and Training Center in Community-Oriented Services for Persons with Spinal Cord Injury, a study is being conducted of age-related changes in persons with spinal cord injury. The study is based upon a $2 \times 2 \times 2$ prospective, longitudinal design that involves 100 participants. The three independent variables are: 1) duration of injury; 2) age when injured; and, 3) measurement of Occasion 1 versus Occasion 2. Three years will intervene between the two measurement occasions. Dependent variables are being assessed in six different life domains (physical well-being, psychological well-being, social integration, independence, productivity, and economic self-sufficiency), and with respect to five moderating factors (social support, health beliefs and practices, environmental supports, perceived control, and mobility). Threats to physical well-being that are being documented include bacteriuria, kidney or bladder calculi, renal insufficiency, pulmonary insufficiency, coronary heart disease, hypertension, spinal arthritis, heterotopic ossification, neuromuscular pain or progressive fatigability, lipid abnormalities, and pressure sores. The psycho-

logical well-being of participants is being compared with norms for the general population in terms of life satisfaction, depression, and perceived psychological stress.

Progress/Methodology—Participants were chosen on a random basis from a cohort of more than 640 persons with spinal cord injury who reside in a 13-county area in southeast Texas that includes the cities of Houston and Galveston. Following a home visit that includes an interview and completion of multiple self-administered instruments, participants undergo a day-long assessment at The Institute for Rehabilitation and Research that includes a physical examination, clinical laboratory assessments, X-rays, a renal scan, and provocative cardiopulmonary evaluation.

Future Plans/Implications—Results of this study will contribute to the identification of risk factors for a number of the age-related problems of persons with spinal cord injury, and to the anticipation of service needs that emerge as these persons grow older. The first wave of data acquisition has been completed, and the second wave will begin in September, 1991.

[503] Life Status Study of Persons with Spinal Cord Injury

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Purpose—Under the auspices of the Rehabilitation Research and Training Center in Community-Oriented Services for Persons with Spinal Cord Injury, this study is being conducted of the life status and service needs of persons with long-term injury of the spinal cord. Life status is being assessed in six domains: physical well-being, psychological well-being, social integration, independence, productivity, and economic self-sufficiency. Variance in each life domain is being explored as a func-

tion of individual difference variables particular to spinal cord injury (e.g., level and duration of injury to the spinal cord) and variables that apply to the general population (e.g., educational attainment and gender). Measures are also being obtained on five variables that are posited to moderate the relationship between the individual difference variables and the life domains. The moderating variables are social support, health beliefs and practices, environmental supports, perceived control of one's life,

and mobility. Where possible, measures have been chosen for which norms are available for the general population so that comparisons can be made.

Progress/Methodology—A cohort was established of persons with spinal cord injury who reside in a 13-county area in southeast Texas that includes the cities of Houston and Galveston. A random sample of 140 persons was drawn from the cohort of more than 640 individuals. Following a home visit that included an interview and completion of multiple self-administered instruments, participants underwent a day-long assessment at The Institute for Rehabilitation and Research that included a physical examination, clinical laboratory assessments, X-rays, a renal scan, and provocative cardiopulmonary evaluation.

Threats to physical well-being that were documented include bacteriuria, kidney or bladder calculi, renal insufficiency, pulmonary insufficiency, coronary heart disease, hypertension, spinal arthritis, heterotopic ossifi-

cation, neuromuscular pain or progressive fatigability, lipid abnormalities, and pressure sores. The psychological well-being of participants will be compared with norms for the general population in terms of life satisfaction, depression, and perceived psychological stress.

Other comparative data concerning social integration, functional independence, productivity, and economic self-sufficiency should contribute to the knowledge base necessary to anticipate the service needs of persons with long-term spinal cord injury.

Future Plans/Implications—This study is based upon a representative sample from a cross-section of persons with longterm spinal cord injury rather than a convenience sample of persons known to a particular service program. Consequently, reasonable estimates can be made of the prevalence of various problems and service needs of persons with long-term spinal cord injury. Data acquisition has been completed and analyses of the data are in progress.

[504] Comparative Rehabilitation Outcomes for Women and Men as Reflected by the National Spinal Cord Injury Database

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Purpose—Under the auspices of the Texas Model Spinal Cord Injury System, outcomes are being compared of men and women whose rehabilitation was provided by model spinal cord injury systems. As a complement to a companion study which has a prospective, longitudinal design, this study consists of retrospective analyses of information in the National Spinal Cord Injury Database. Gender-related differences will be assessed in rehabilitation outcomes that exist 12 months following injury at a time when these persons have resumed their lives in the community. The principal dependent variables are at the levels of handicap (occupational/educational status, marital status, and place of residence [nursing home or otherwise]), disability (attendant care utilization), secondary complications, and unplanned service utilization (number of admission days in system and non-system hospitals).

Progress/Methodology—All women who were enrolled in the database between 1984 and 1986 will be included who were age 16 or older at the time of injury, who were admitted for inpatient rehabilitation no more than 60 days following injury, and whose records contain data on the variables described above. These subjects will be matched with an equal number of males in terms of the level and completeness of the spinal cord injury, age at injury, and preinjury occupational/educational status.

Future Plans/Implications—The goal of this project is to evaluate the effectiveness of services of the model spinal cord injury systems in terms of comparative outcomes for women and men at their first anniversary postinjury. Data analyses began in October, 1990.

[505] A Comparative Longitudinal Study of Rehabilitation Outcomes for Women and Men with Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Conducted under the auspices of the Texas Model Spinal Cord Injury System, this study addresses the acknowledged void of scientifically validated information about the rehabilitation-related needs and outcomes that distinguish men and women who incur spinal cord injury. Using a prospective longitudinal design, similarities and differences between women and men undergoing inpatient rehabilitation and follow-up services will be documented in terms of functional recovery, prevalence and severity of secondary complications, psychological well-being, and utilization of services. Variables to be monitored that are distinctive to women will include selective aspects of social role performance, sexuality, and obstetrical and gynecological status. A related objective is to identify similarities and differences between women and men in their preinjury characteristics, and characteristics of their inpatient rehabilitation experience that forecast postdischarge health status, degree

of disability, social role performance, as well as the kinds and extent of service utilization.

Progress/Methodology—A minimum of 30 females who are admitted for rehabilitation into the Texas Model Spinal Cord Injury System will be matched with the same number of male patients in terms of level and completeness of spinal cord injury, age at injury, and preinjury vocational/educational status. In addition to data that reflect participants' inpatient rehabilitation experience, follow-up data will be obtained at 6-, 12-, and 24-months postinjury.

Future Plans/Implications—The resulting data will serve to evaluate the comparative effectiveness of model spinal cord injury system services in terms of interim and post-rehabilitation outcomes for men and women. Data acquisition began in November, 1990.

[506] Collaboration Between Model Spinal Cord Injury Systems and Independent Living Centers in Facilitating Independent Living by Persons with Recently Incurred Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Under the auspices of the Texas Model Spinal Cord Injury System, a project is being conducted to develop, implement, and systematically evaluate a cooperative, model reentry program involving a medical rehabilitation program and an independent living center. Building upon the experience of the University of Michigan spinal cord injury system, this project will assess the expectation that by providing coordinated community living reentry services by a medical rehabilitation program and an independent living center during the post-discharge period, life-adjustment will be enhanced during that period and, in turn, long-term adjustment will be enhanced as well. Life-adjustment will be evaluated in

terms of the individual's physical and subjective well-being, psychological and functional independence, productivity, social integration, and intensity of health services utilization, both planned and unplanned.

Progress/Methodology—A cycled treatment and comparison group design will be used. Specifically, for one 4-month period, all eligible spinal cord injury inpatients will participate in the model reentry program. For the succeeding 4-month period, all eligible patients will receive conventional reentry services. Over the two-year period during which patients are enrolled in the study, 50 patients will be enrolled in the model reentry program,

and 50 patients will be enrolled in the conventional program. The experience of participants in both programs will be tracked over a 2-year period following discharge from the spinal cord injury center.

Future Plans/Implications—This project represents an attempt to confirm the expectation that by providing

coordinated community living reentry services by a medical rehabilitation program and an independent living center during the post-discharge period, life adjustment will be enhanced during that period and, in turn, long-term adjustment will be enhanced as well. Data acquisition began in January, 1991.

[507] Direct Approach to Synaptic Organization of Nociception

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—This project was devised with the specific aim of clarifying whether spinal modulation of nociceptive sensory information, transmitted by peptidergic sensory fibers, occurs at a pre- or post-synaptic site. Our hypothesis, based on the available evidence, is that both sensory fibers containing substance P and enkephalinergic spinal neurons act postsynaptically on glomerular or non-glomerular dendrites of nociception-driven dorsal horn neurons. For that purpose, a unique combination of ultrastructural immunocytochemistry with intracellular recordings and injections of nociception-driven neurons will be used. This type of labeling is the only one that can provide a direct answer to the hypothesis outlined above, and has never been used before in a systematic way.

Methodology—All the experiments will be carried out in adult cats under α -chloralose anesthesia. Nociception-driven neurons of lamina I of the lumbar spinal cord will be injected intracellularly with horseradish peroxidase

(HRP). The animals will be fixed by vascular perfusion and the relevant segments of the spinal cord sectioned in a vibratome and processed for the demonstration of peroxidase. The slices containing intracellularly injected cells will be further processed for the simultaneous demonstration of substance P and enkephalin immunoreactivities at the electron microscopic level. The sensory origin of the substance P fibers will be assessed in some animals by injections of tritiated amino acids in the dorsal root ganglia, and by combining immunoreactivities for calcitonin gene-related peptide, γ -Aminobutyric acid, serotonin, choline acetyltransferase, and somatostatin, in combination with radioimmunocytochemistry for substance P or enkephalin, and electrophysiology will also be carried out.

Implications—This research is expected to bring important new information on the modulation of pain in the spinal cord.

[508] Spinal Somesthetic Pathways (Monkeys)

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Purpose—This project has three major goals. The first goal is the improvement of neurological diagnosis of spinal cord injury by defining the sensory capacities that depend critically upon transmission along the dorsal spinal columns. This major somatosensory pathway has been investigated thoroughly by anatomical and physiological techniques, but psychophysical investigations are

needed to determine the functional significance of organizational features that have been described.

The second goal is an analysis of the mechanical factors that determine the sensitivities of cutaneous receptors that can be described by application of video analysis techniques to microscopic views of the skin during indentation. This analysis will focus on the

non-hairy (glabrous) skin of primates that is specialized for exquisite tactile sensitivity.

Goal three is to improve understanding of the participation of spinal cord circuitries in the control of pain; therefore, pharmacological compounds will be introduced directly on the spinal cord (intrathecally), and both sensory and motor capacities will be evaluated thoroughly. By comparing the effectiveness of a variety of opiate agonists in modulating pain reactions without producing other effects, improved methods of pain therapy can be suggested.

Methodology—The proposed studies will be conducted with monkeys, because the spinal pathways are quite similar among primates, but differ considerably between primates and other mammals. The stimuli utilized in these are brief, noninjurious, and easily tolerated by monkeys and humans. This is a multidisciplinary approach within the neurosciences, involving direct correlations of anatomical and physiological data with highly quantitative evaluations of sensory thresholds and motor reactions to precisely controlled somatosensory stimuli.

[509] Rehabilitation Technology Needs Assessment of Farmers and Ranchers with Spinal Cord Injuries

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—The objective of the project is to increase the benefits of appropriate assistive technology to farmers, ranchers, and agricultural workers with spinal cord injury, and members of their families. The project has two basic goals: 1) to develop an estimate of the number of individuals with spinal cord injury who live and/or work on American farms and ranches, or who are involved in some aspect of agricultural production; and, 2) to complete a rehabilitation technology needs assessment, with a special emphasis on agricultural worksite accessibility of individuals with spinal cord injury.

Methodology—Rural and farm population data will be extrapolated to estimate the number of persons with spinal cord injury involved in agriculture. Site visits will be made to farmers with spinal cord injury in 10 states.

A survey for needs assessment for agricultural workers with spinal cord injury will be developed and field-tested.

Progress—The needs assessment survey has been distributed to 225 farmers with spinal cord injury. The response rate for completing the survey was 51% as of June 1990.

Results—A mailing list of farmers with spinal cord injury has been developed. Photographs of worksite modifications have been obtained and descriptions written.

Future Plans/Implications—Analysis of the needs assessment survey will be conducted. A general technology needs assessment will be developed. During the second year of the project resource material for farmers with spinal cord injury will be prepared.

[510] Physiological Mechanisms of Spinal Cord Plasticity

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—The purpose of this project is to identify sites where plasticity of the spinal cord can occur, and the ways in which it can affect spinal cord function.

Methodology—In most experimental studies of spinal cord plasticity, spinal cord trauma is mechanically

induced, with the result that complex and diffuse changes are initiated, making study of subsequent plasticity difficult. In the present study, a nontraumatic method of eliciting spinal cord plasticity has been used. Animals are trained in a task for which they are rewarded for changing the size of a simple spinal reflex. Over the course of

several weeks, animals are able to increase or decrease the size of this reflex, depending on the requirements of the task.

Progress—Modification of the strength or the organization of neuronal connections is being studied by examining the intrinsic properties of individual neurons comprising this spinal reflex pathway and the strength of their synaptic influences on each other.

Results—Changes in reflex behavior appear to be long-lasting. The site of plasticity has been identified to be within the spinal cord itself.

Future Plans/Implications—These studies should localize and define the changes elicited in the spinal cord by the reflex modification task and should begin to reveal the mechanisms that create these changes. The work may

help to trigger efforts to develop new therapeutic techniques for promoting recovery of useful function after spinal cord injury. This work is significant in that it represents the development of an simple animal model to study memory traces.

Recent Publications Resulting from This Research

Memory Traces in Spinal Cord. Wolpaw JR, Carp JS, Trends in Neurosciences 13(4):137-142, 1990.

Operant Conditioning of H-Reflex in Freely Moving Monkeys. Wolpaw JR, Herchenroder PA, J Neurosci Methods 31:145-152, 1990.

Motoneuron Physiology After H-Reflex Operant Conditioning: Initial Studies. Carp JS, Wolpaw JR, Neurosci Abstr (in press).

Operant Conditioning of Triceps Surae H-Reflex: The First Days. Wolpaw JR, Neurosci Abstr (in press).

Triceps Surae Motoneurons and Ia Afferent Connections: Further Anatomical Studies. Lee CL, Carp JS, Wolpaw JR, Neurosci Abstr (in press).

[511] Electrophysiological Basis for Contraction in the Bladder

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—The purpose of this study was to characterize the activity of interstitial cells of Cajal (ICC), which are hypothesized to be pacemaker cells, and which are found in colonic and bladder muscles. Additionally, the study will determine the effects of various drugs on the rhythmic electrical activity of ICC, which are essential for normal motor functioning of the colon and bladder.

Progress/Methodology—Interstitial cells of Cajal from colon segments and bladder in dogs were identified through morphological examination. Excitability of these cells was studied using a whole-cell patch clamp technique. Experiments were performed to determine whether isolated ICC were capable of spontaneous rhythmic activity. In addition, whole bladder electrophysiological studies were conducted using standard

electrophysiological techniques to record intracellular membrane potential.

Results—Electrical recording from ICC cells indicated that they were indeed electrically active, producing a series of rhythmic electrical events. Excitatory input in the whole bladder appeared to be largely cholinergic; however, it appeared that a noncholinergic excitatory transmitter was also released upon stimulation.

Future Plans/Implications—Further work will characterize the role of ICC in generating electrical activity and the development of specific probes for ICC cells. The results of this project should provide a scientific rationale for the development of new drugs to help patients with functional motor problems of the colon and bladder.

[512] Intrathecal Baclofen for Intractable Spinal Spasticity

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Sponsor: *Physicians' Services Incorporated Foundation*

Purpose—Reports indicate that intrathecal baclofen has effectively and safely reduced spasticity, as opposed to conventional therapeutic measures. It has been embraced as a treatment outside Canada, although a careful evaluation of its efficacy is lacking. Such treatment requires permanent implantation of a costly drug administration device similar to the insulin pumps currently in use, and therefore requires careful appraisal. This preliminary study is to demonstrate whether there is a significant treatment effect that can be reproduced and maintained without serious side effects.

Progress/Methodology—Facilities in the Rehabilitation Engineering Department of the Rehabilitation Centre were set up to record electromyograms of the lower limbs. Software was developed to record the data

and a special device was built to induce a reflex in the leg.

Subjects are recruited from the spinal cord rehabilitation unit at the Rehabilitation Centre and the Multiple Sclerosis Clinic at Ottawa General Hospital. They are admitted to the neurological intensive care unit at the Ottawa General Hospital where a percutaneous lumbar subarachnoid catheter is introduced under local anaesthesia. Baclofen is administered through the catheter. Outcome measurements include: muscle tone, bladder function, overall motor function, and self care. Evaluations include self-assessment by the subjects, clinical examinations, and physiological recordings.

Future Plans—Recruitment and treatment should be completed in 1991.

[513] Health and Functional Status of Aging SCI Persons

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Sponsor: *Rocky Mountain Regional Spinal Injury System; National Institute on Disability and Rehabilitation Research*

Purpose—This two-pronged collaborative study is designed to identify and evaluate secondary complications and disabilities which occur in people living many years with spinal cord injury (SCI). Objectives of this effort include: 1) determining causative factors of complications that are amenable to intervention; and, 2) developing intervention methodologies to prevent and minimize the severity of these secondary disabilities.

Methodology—Craig Hospital is collaborating with the National Spinal Injury Centre in Aylesbury, England, and the Regional Spinal Injury Centre in Southport, England, both of which have a 45-year history of providing comprehensive rehabilitation and follow-up services to the military and civilian SCI persons in the United Kingdom. An unbiased sample of SCI cases that were traumatically injured more than 20 years ago in a specified geographic region in proximity to the two SCI centers and admitted within one year for treatment, is being used. Nine

hundred and thirty four persons, of whom 394 are surviving, meet the narrow study criteria. In addition to thorough analysis of the medical records of all study cases, surviving individuals will be located to obtain a current medical assessment and to complete a comprehensive interview regarding medical and psychosocial history.

Progress—Approximately 300 individuals completed the comprehensive medical assessment and interview by January 1, 1991. In addition, Craig Hospital is leading five other federally designated United States model spinal injury treatment centers in collaborative research to document the nature and extent of medical complications, functional losses, and psychosocial effects which accompany aging with SCI. A companion study will focus on Craig Hospital clients injured more than 20 years ago.

Implications—Data from the 300 individual participants in the British collaborative study will be analyzed and

compared with normative data from longitudinal gerontological studies in order to determine the relative rate of health and functional decline of spinal cord injured individuals in comparison with the able-bodied population. As indicated by the data, specific future studies may be conducted to further examine particular aging issues and to test the effectiveness of the proposed treatments, preventive techniques, or interventions, and to explore new models of service provision.

Future Plans—A computerized summary medical record to aid in lifetime care and research will be developed. Also, a prospective longitudinal database which comprehensively describes the aging of organ systems, the incidence and prevalence of medical complications, and associated functional decline occurring throughout the

lifetimes of people with spinal cord injuries will be established. Valid and reliable measures of disability, handicap, and quality of life will be developed and used to document changes over time. This database will facilitate comparison of the aging of individuals with SCI with the aging of able-bodied persons. It will allow for analysis of the interactive impact of chronological age and duration of spinal cord injury. The differential impact of aging for males and females, and those who sustained their spinal cord injuries in youth versus those who were injured later in life, also will be examined.

Finally, Craig Hospital is planning a national consensus conference to disseminate the latest knowledge in aging with spinal cord injury and to establish research and long-term care goals for the future.

[514] Shepherd Spinal Center's Leisure Education Program: An Evaluation

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Sponsor: *Shepherd Spinal Center Research Review Committee*

Purpose—Social integration following spinal cord injury (SCI) has become a topic of interest and concern in recent years. It has been found to be the most significant determining factor in survival versus death after spinal cord injury. A marked decrease in the number of social contacts, frequency of entering the community, and number of roles played in the community following SCI has been noted with concern. Work on intervention strategies that increase the function of persons with spinal injury in interpersonal, vocational, and community activities has been called for.

Progress—Since 1981, the Therapeutic Recreation Department has implemented a Leisure Education Program (LEP) in an effort to facilitate social integration postdischarge. The goals of the program are: 1) to locate community resources; 2) discover personal leisure attitudes and values; 3) assess pre-injury lifestyle patterns and changes that will occur; 4) explore new lifestyle options and begin to develop new skills; 5) develop skills related to leisure, such as

assertiveness, problem-solving, and social skills; and, 6) develop and finalize a discharge leisure plan. This research study was designed to evaluate the effectiveness of the LEP. In doing so, four major questions were addressed with 60 experimental subjects: 1) Are the outcomes congruent with the program's intended objectives? (as measured by a knowledge exam); 2) What effect does participation have on participants intended future involvement in leisure activities? (as measured by the Leisure Activities Blank); 3) Does participation in the LEP have an effect on social integration patterns postdischarge? (as measured by phone interview 6 to 8 months postdischarge); and, 4) What are the correlations between the demographic variables (age, sex, level of injury, and amount of time in rehabilitation program) and the LEP outcomes?

Recent Publications Resulting from This Research

A Survey of Post-Acute Spinal Cord Patients: Medical, Physiological and Social Characteristics. Anson C, Shepherd C, Trends: Research News from Shepherd Spinal Center, March, 1990.

B. Treatment and Rehabilitation

[515] Development and Testing of New Spinal Implant Systems

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Sponsor: VA Rehabilitation Research and Development Service (Project #B365-2RA)

Purpose—The overall purpose of this grant is to better define the dynamic biomechanical properties of retrieved laboratory animal spines, to conduct cyclic testing on surgical implant systems *in vitro*, and to evaluate new implant systems *in vivo* in primates for functional safety and efficacy. The data would then be used to design, test, and apply new devices useful for surgical reconstructions and rehabilitation within veteran patient populations.

Progress/Methodology—Laboratory model analyses have been extended to include preliminary biomechanical models and test systems on the MTS Bionix 858 dynamic testing system. Dynamic fatigue compression, torsion, and combined compression-torsion testing systems have been established, quantified, and applied to swine and primate spines. A three-dimensional TV and computer-based methodology has been further defined and calibrated for motion analyses of whole spines and adjacent vertebral bodies. One PhD dissertation (R. Moeini) and one MS thesis (G. O'Connell) in Biomedical Engineering are being coordinated within the VA Medical Center project activities. Dr. Lemons is serving as committee chairman for both students. An anterior implant has been redesigned to include titanium alloy and a final shape to accommodate fabrication and clinical placement. Baboon cages have been obtained and the surgical placements of the implants in primates or swine were initiated in 1990.

The *in vivo* baboon studies have been significantly delayed because of changes in animal welfare requirements, the closure of primate facilities at Wright-Patterson Air Force Base necessitating a move to the University of Alabama at Birmingham, and the requirement to procure adequate caging facilities. Testing on pedicle-based spinal fixation systems has been completed and the results presented at a national meeting. These studies showed that spinal pedicle-based rod and plate systems applied to a vertebrectomy model loaded under axial compression and torsional fatigue conditions did not provide stability of fixation. The spinal implants in this model system exhibited loosening and mechanical damage during testing.

Future Plans—The current plan is to extend the *in vitro* biomechanical testing to include: new and current posterior systems, the new anterior spinal implant, and retrieved spines containing the previously implanted anterior spinal device. *In vitro* and *in vivo* phases of the program should be completed in 1991. The affiliated graduate student research programs should be completed during the third year of this grant period. Since several of the proposed posterior systems and composites could not be studied within this grant period, a new grant proposal for continuing the investigation will be submitted during 1991.

[516] Management of the Musculoskeletal Complications of Spinal Cord Injury

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Sponsor: VA Rehabilitation Research and Development Service (Project B576-RA)

Purpose—This project is designed to develop and apply newly discovered, bone cell-specific serum markers to clinical studies of musculoskeletal assessment in patients with trauma and illness involving the spinal cord. The

methods to be used involve new immunoassay procedures with increased sensitivity and defined specificity for classical skeletal markers such as bone alkaline phosphatase (BAP) and bone acid phosphatase (BAP) and new

skeletal markers such as bone Gla protein (BGP, osteocalcin) and its derived peptides. It is our hypothesis that these procedures will assist in the design and evaluation of treatment regimens for patients with spinal cord injury and disease. We should be able to identify those regimens that are beneficial (or deleterious) for optimal rehabilitation of the patient.

In accord with the recommendations of the Review Panel on Spinal Cord Injury, we are focusing on the development and validation of these serum markers and are not yet conducting clinical studies.

Progress/Methodology—We have made considerable progress in each component of our proposal during the first 5 months of the project. For BAP measurements, we have developed a protocol two-site radioimmuno-metric assay specific for this protein. To confer specificity for BAP, the assay utilizes one immobilized antibody and another radiolabeled antibody to the enzyme. In validation studies, we were able to demonstrate that BAP was elevated in patients with Paget's disease, 365 U/ml, but indistinguishable from normal in patients with liver disease. In these validating studies, BAP correlated with total alkaline phosphatase (TAP) ($r=0.96$), and less so with BGP ($r=0.60$). The corresponding correlation between BGP and TAP was 0.57. Our results demonstrate both similarities and differences of BAP with other skeletal indices. This assay for BAP will thus be uniquely useful in the assessment of patients with calcium and skeletal disorders. It distinguishes BAP from liver alkaline phosphatase and should provide a new clinical tool for studying bone metabolism in patients with spinal cord injury. For bone Gla protein (BGP, osteocalcin), we have initiated a program to identify monoclonal antibodies specific to different sequences of the molecule that are compatible with a two-site assay format.

For BAcP, we have developed a purification scheme for the protein that should permit antibody development. Pieces of cleaned human bone are ground in a stainless steel blender. Two volumes (ml/g) of 50 mM tris-acetate with pH 7.8, 100 mM NaCl, 0.1% Triton X-100, 1 mM PMSF are used to homogenize the bone powder. Bone extract is then subjected to cation-exchange chromatography (ZetaChrom SP sulfopropyl chemistry). Cationic proteins are eluted with 500 mM NaCl. Eluted fractions high in tartrate-resistant acid phosphatase activity are pooled and chromatographed by SDS-PAGE. Samples are solubilized in sample buffer and run under non-reducing conditions on BioRad 7.5% Tris-HCl ReadyGels. Immediately following electrophoresis, gels are developed at 37 degrees C for tartrate-resistant acid phosphatase activity in 120 mM acetate buffer, pH 5.4 containing 10 mM l-tartaric acid and 1 mg/ml 1-naphthyl phosphate as substrate. Reaction product is visualized by conjugation with 0.2 mg/ml Fast Garnet GBC in the reaction solution. This purification scheme has allowed us to identify candidate species of BAcP for assay development.

Preliminary Results/Implications—The first 5 months of this project has resulted in significant advances in all stages of our proposed research. The above-described progress will support our goal to develop methods that will ultimately assist in the clinical management of patients with spinal cord injury.

Recent Publications Resulting from This Research

A Two-Site Immunoradiometric Assay Specific for Human Bone Alkaline Phosphatase Correlates with Other Indices of Osteoblast Function. Deftos LJ, Weisman MG, Hill CS, *J Bone Min Res* 55:A642, 1990.

[517] Compression and Ischemia As It Affects Spinal Cord Injury

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Sponsor: VA Rehabilitation Research and Development Service (Project #B535-RA)

Purpose—The pathophysiology of the injuries to the spinal cord and cauda equina is poorly understood. Injury due to mechanical compression and ischemia is common, but not well delineated. The purpose of this project is to gain increased knowledge of the effects of various insults to the spinal cord and nerve roots.

Progress—Our progress in the past year has been to complete the examination of the effects of hypotension during compression and recovery, and hypotension during compression with normotensive recovery at the level of the cauda equina. These results were compared with our past work, the effects of normotension with compression.

A two-level coccygeal laminectomy was performed on 20 mini-pigs weighing 40 ± 6 kg. A polyethylene balloon was placed between the cauda equina nerve roots and a rigidly secured plexiglass plate. Electrodes were positioned proximal and distal (control) to the compression device, and electrodes were placed in the tail to allow electrophysiologic monitoring. Blood pressure was reduced to a mean of 60 mmHg (normotensive mean 94 ± 5 mmHg) using sodium nitroprusside. The spinal nerve roots were then compressed at 0 (sham), 50, 100, or 200 mmHg for 2 hours followed by a 90-minute recovery period. Results were compared to compression in normotensive animals to assess the effect of hypotension and compression on nerve root function. The experiment was then repeated, but using normotension during the recovery period. Results were then compared to compression with hypotension throughout to assess the effects of hypotension and compression with a normotensive recovery period on nerve root function.

Results—Hypotension during compression and a hypotensive recovery period. This study demonstrated an independent effect of hypotension on cauda equina nerve roots undergoing acute graded compression. Compressive injury represents a combination of ischemic and direct mechanical damage. Our data suggest that hypotension has its major impact on nerve root function at lower levels of compression. At higher compression levels (above the mean arterial pressure), ischemia is complete and the effect of hypotension is seen predominantly during the recovery period.

Hypotension during compression and a normotensive recovery period. This study demonstrated a significant improvement in nerve root recovery with normotensive recovery conditions following a combined hypotensive and compressive nerve root insult. Sensory

(afferent) fibers are more sensitive to hypotensive effects in the recovery period.

Future Plans—Our future plans are to continue to examine the effects of hypertension with compression, hypoxia with compression, and complete vascular ischemia at the level of the cauda equina, after which we plan to repeat the same series of experiments at the level of the conus medullaris, and then at the level of the thoracic spinal cord. This is in an effort to gain increased knowledge concerning the underlying causes of injuries to the spinal cord and spinal nerve roots.

Recent Publications Resulting from This Research

- Differential Recovery of Motor and Sensory Nerve Root Conduction Following 2 or 4 Hours of Graded Compression of the Pig Cauda Equina (Abstract). Pedowitz RA et al., International Society for the Study of the Lumbar Spine, Kyoto, Japan, 17-18, 1989.
- The Effects of Magnitude and Duration of Acute Compression Upon Impulse Conduction in the Pig Cauda Equina: Differential Recovery of Sensory and Motor Nerve Roots (Abstract). Pedowitz, RA et al., in Transactions of the 35th Annual Meeting, Orthopaedic Research Society, Las Vegas, 14:428, 1989.
- Graded Compression of the Pig Cauda Equina: Differential Recovery of Efferent and Afferent Spinal Nerve Root Conduction (Abstract). Pedowitz RA et al., North American Spine Society, Quebec City, Canada, 68-69, 1989.
- The Effect of Hypotension and Acute Graded Compression on Cauda Equina Nerve Root Function (Abstract). Cohen MS et al., in Transactions of the 36th Annual Meeting, Orthopaedic Research Society, New Orleans, 15 (Sect 1):122, 1990.
- The Effect of Hypotension and Acute Graded Compression on Cauda Equina Nerve Root Function (Abstract). Garfin SR et al., American Spinal Injury Association, Orlando, 35; International Society for the Study of the Lumbar Spine, Boston, 23; and, North American Spine Society, Monterey, CA 43, 1990.
- Changes in Spinal Nerve Root Impulse Conduction Induced by Acute Graded Compression of the Pig Cauda Equina. Rydevik BL et al., Spine (in press).
- Nerve Roots of the Cauda Equina: The Effects of Hypotension and Acute Graded Compression on Cauda Equina Nerve Root Function. Garfin SR et al., J Bone Joint Surg (in press).

[518] Electric Field Distribution in Experimentally Injured Spinal Cord: Improved Function After Electrical Stimulation of Injured Spinal Cord

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Sponsor: VA Rehabilitation Research and Development Service (Project #B423-RA)

Purpose—This study evaluates the effect of electrical stimulation upon the functional status of injured spinal cord.

Progress/Methodology—A contusion model of injury is being investigated. To ensure that both stimulated and

control animals are injured to the same degree, the trauma device has been further refined and standardized, incorporating features of designs described in the literature. This includes an adjustable magnetic vertebral stabilizer, an in-line computer-interfaced strain gauge, and an independent, pre-positionable Teflon impounder head. Our findings suggest that the resulting injury is more controlled and reproducible, making conclusions regarding improvement after treatment more significant.

Six cats weighing from 2 to 2.5 kg were anesthetized with an intramuscular injection of ketamine and xylazine. A laminectomy was performed at T8-T10 and the spinal cord was subjected to a contusion injury at the T9 level using a modified weight drop method which delivers an impact force of 75 to 85 newtons to the spinal cord. These animals received daily postoperative care in accord with the American Association for Accreditation of Laboratory Animal Care (AAALC) guidelines. Of these six cats, three received platinum disc electrodes which were inserted 2 cm above and below the level of the lesion and connected to an implantable pulse stimulator.

The cathode and anode were placed caudally and rostrally, respectively, to the injury site. The electrodes were placed epidurally with the anode on the dorsal surface and the cathode on the ventral surface of the spinal cord. The electrical stimulation consisted of $20\mu\text{A}$ peak current of 0.5 ms duration with a frequency of 10 Hz.

Preliminary Results—For 6 to 7 months, the animals were examined for behavioral performances using a wide range of tests. At the end of the test period, the two cats with stimulators displayed tactile placing responses and

partial weightbearing in the hindlimbs. One of the three electrically stimulated cats walked or pushed on its "knuckles" while keeping its knees close to the ground. The second cat appeared to be voluntarily pushing slightly with its hindlimb. None of the cats in the control non-stimulated group showed any tactile placing responses or any weightbearing in the hindlimb.

Electrophysiological recordings showed the absence of somatosensory and spinal evoked responses in all animals after trauma following stimulation of the tibial nerve. However, in the stimulated cat showing the most behavioral recovery, responses were present at 120 days post-trauma while absent at 60 and 90 days post-trauma.

Future Plans—Further studies are planned using controlled injury and electrical stimulation methods as well as objective assessment techniques to determine whether or not there is a clear functional benefit of applied electric fields in spinal cord injury.

Recent Publications Resulting from This Research

Electrical Stimulation in the Treatment of Experimental Traumatic Spinal Cord Injury. Khan T, Myklebust J, International Symposium on Biomagnetism, Magnetobiology and Magnetotherapy, Newport, 1989.

Improved Micturition with Direct Current Stimulation of the Spinal Cord in the Spinal Cat (Abstract). Khan T et al., Soc Neurosci 15:630, 1989.

Current Distribution in Normal and Injured Cat Spinal Cord. Zaug CA et al., in Proceedings of the 10th Annual Meeting of the Bioelectrical Repair and Growth Society, 1990.

Effects of Two Electrode Configurations on Current Distribution in Cat Spinal Cord. Zaug CA et al., in Proceedings of the 10th Annual Meeting of the Bioelectrical Repair and Growth Society, 1990.

[519] Wheelchair Graded Exercise Test for Patients with Lower Limb Disabilities

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Sponsor: VA Rehabilitation Research and Development Service (Project #B398-RA); Vaughan Chapter of the Paralyzed Veterans of America

Purpose—The primary purpose of this 2-year study was to develop improved methods for the objective evaluation of the cardiorespiratory health and fitness of spinal cord injured (SCI) and other patients with lower limb disabilities. These evaluations will provide baseline data useful in judging the effectiveness of patient rehabilitation, cardiorespiratory training programs, and in charting any

progressive deterioration of health resulting from disability-imposed inactivity. Our objectives were to: 1) establish standardized maximal and submaximal wheelchair graded exercise tests to accurately measure the cardiorespiratory fitness of patients restricted to the manual wheelchair; 2) evaluate the sensitivity of the testing system for detecting abnormal cardiovascular and

pulmonary responses to exercise stress in SCI and other persons with lower limb disabilities; and, 3) compare data resulting from the experimental wheelchair testing protocol with data obtained from conventional arm crank ergometry.

Progress—Fifty-one males (17-69 years old) with tetraplegia, paraplegia, amputations, and other lower limb disabilities completed one continuous and one discontinuous maximal wheelchair graded exercise stress test on the Wheelchair Aerobic Fitness Trainer (WAFT) and one continuous test on the arm crank ergometer (AC). Subjects with complete or incomplete SCI were assigned to three experimental groups: upper-level injury (ULI), C₅-T₃ (n=12); mid-level injury (MLI) T₄-T₁₀ (n=19); and, lower-level injury (LLI) below T₁₀ and persons with lower limb fractures (n=20). Stages were 3 minutes with power output increments of 16 watts per stage for the AC and 7 for the WAFT. Significant between-group mean differences were found in peak measures of heart rate (HR), oxygen uptake ($\dot{V}O_2$) and minute ventilation (\dot{V}_E) for all experimental conditions. Peak measures of HR, $\dot{V}O_2$ and \dot{V}_E during AC and WAFT exercise tests were significantly correlated ($p < 0.001$). Correlation coefficients for continuous and discontinuous WAFT tests at the peak of exercise for the same parameters were also significant ($p < 0.001$). Correlation coefficients showed a strong relationship between differentiated ratings of perceived exertion for AC and WAFT continuous exercise ($r=0.94$). It was concluded that the WAFT provides a valid method for evaluating the cardiorespiratory fitness of persons with SCI and other lower limb disabilities.

A comparison of maximal arm crank and continuous wheelchair exercise performance of lower limb disabled veterans from this study and subjects from previously published research demonstrates that the veterans in the MLI and LLI groups produced consistently lower power outputs and metabolic values for both arm crank and wheelchair ergometry. This observation may not be

considered remarkable given the low level of chronic physical activity of these subjects and that the majority of comparison data has been collected from individuals who are a decade younger and regularly involved in wheelchair sports. However, there is reason for concern regarding the cardiorespiratory health of the aging middle-aged sedentary person with lower limb disabilities.

We continue to gather data to demonstrate that a wheelchair graded exercise test will provide a sufficient challenge to the cardiovascular and pulmonary systems of lower limb disabled patients with suspected coronary artery disease (CAD). The need for a noninvasive upper body exercise stress test with an acceptable degree of sensitivity and specificity for the detection of CAD in persons with lower limb disabilities is increasing; the WAFT and test protocol may meet this need. Seventeen lower limb disabled veterans (44-81 years old) with suspected CAD were referred to our laboratory for wheelchair stress testing; eight had true positive ECGs substantiated by either cardiac catheterization or echocardiography. No patients had a false positive test, seven patients had true negative and two patients false negative tests. The two false negative findings were attributable to the influence of drugs used to regulate the inotropic and chronotropic states of the heart. We are currently developing new standardized procedures for combining stress echocardiography with wheelchair ergometry.

Recent Publications Resulting from This Research

- Interactive Video Games and Real Time Displays for the Wheelchair Aerobic Fitness Trainer. Flaherty BP, Robinson CJ, Langbein WE, in Proceedings of the IEEE/Engineering in Medicine and Biology 11th Annual Conference, Seattle, 1989.
- Speed-Torque Calibration of the MAGTURBOtm and Wheelchair Aerobic Fitness Trainer. Langbein WE, Robinson CJ, Kynast LT, in Proceedings of the IEEE/Engineering in Medicine and Biology 11th Annual Conference, Seattle, 1989.
- Validation of a New Ergometer for Graded Exercise Testing of Persons with Lower Limb Disabilities. Langbein WE et al., in Proceedings of the American Heart Association 62nd Scientific Sessions—Medical Research, Nursing Research, New Orleans, 1989.

[520] Interactive Videodisk Training for Self-Care Skills

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Sponsor: VA Rehabilitation Research and Development Service (Project #B451-RA)

Purpose—Between one-third and one-half of people with spinal cord injuries are rehospitalized in any given follow-up year. The average annual cost for each rehospitalization can range from \$6,700, if surgery is not required, to \$20,000, if surgery is required. The incidence of rehospitalization due to preventable complications can be decreased with appropriate instruction in self-care skills. Such instruction can also hasten people's progress toward adaptation to their disability and personal independence.

Traditional methods of health-care education such as personalized instruction by a health-care professional, self-instruction from written or audiovisual materials, participation in learning groups, or interaction with other disabled persons are often ineffective. The success of such programs may be influenced by factors such as the person's psychosocial, economic, or educational status; the extent of involvement by health-care professionals; and the instructional material or methods. Although some of these factors can be controlled and improved, others cannot. Accordingly, health-care institutions are faced with the difficult problem of teaching valuable skills to people with diverse socioeconomic backgrounds, attitudes, and skills, using staff who may have little time to teach them.

We believe that this problem may be resolved by augmenting traditional education programs with interactive learning technology. Technologies such as computer-

assisted instruction (CAI) or interactive-videodisk instruction (IVI) have several advantages as adjuncts to traditional educational methods. People with diverse socioeconomic and educational backgrounds can learn at their own pace. The novelty of interacting with a computer may provide motivation for learning. CAI or IVI may also be more effective than personalized instruction for teaching difficult or emotion-laden subjects, since they are impersonal and nonthreatening. Interactive learning technologies also free staff to give personalized instruction to people who need it.

Progress/Future Plans—We have developed a menu-driven authoring package for IBM-compatible personal computers that allows someone with marginal computer skills to develop highly interactive instructional material. The authoring system provides the user with interfaces to routines for creating graphics, computer-generated speech, menus, two- or four-alternative questions, and routines for controlling commercial videodisk players. It also provides the user with the ability to establish the sequence of instructional material, thus providing him or her with the ability to create complex scenarios with feedback to the student.

We have developed an instructional series on skin care and will soon be testing its efficacy as an adjunct to traditional instructional methods for self-care skills in a population of persons with spinal cord injuries.

[521] Urinary Bladder Stimulation Following Spinal Cord Injury

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Sponsor: VA Rehabilitation Research and Development Service (Project #B441-2RA)

Purpose—After spinal cord injury, control of bladder function is usually lost. This project's goal is to learn more about the mechanism of bladder dysfunction following spinal trauma and to use this knowledge

to develop ways to manage urinary functions following injury. Methods of stimulating sacral nerves, the pelvic floor, and the bladder directly are under investigation.

Progress—In the anesthetized spinal cord injured cat (T-1), we have compared direct bladder stimulation to sacral nerve stimulation. During terminal procedures, 10 weeks post-spinal cord injury, direct bladder stimulation was conducted with four teflon-coated, “single knot” electrodes inserted in the wall with a needle above the ureters (Cooner wire). Sacral nerve stimulation was conducted with previously implanted needle electrodes inserted into the sacrum (Pisces Quad, Medtronic). In the four male cats investigated, direct bladder stimulation was superior to sacral nerve stimulation because it induced voiding both during and after stimulation, whereas sacral nerve stimulation only induced voiding after stimulation. Voiding rates were also higher with direct bladder stimulation than with sacral nerve stimulation when similar peak bladder pressures were induced. These results show that in the anesthetized animal, direct bladder stimulation can induce effective bladder contractions and does not increase urethral resistance as much as sacral nerve stimulation. We are currently developing an instrumented cat model for chronic recording in the unrestrained animal. This instrumentation will allow us to compare direct bladder stimulation to sacral nerve stimulation in the unanesthetized animal.

Repetitive, spontaneous bladder contractions occurred when the bladder was full in the unanesthetized spinal cat, 4 to 10 weeks after injury. Both sacral nerve and pelvic floor stimulation techniques were investigated to

inhibit the contractions. Stimulating currents that induced pelvic floor and anal contractions were generally effective for inhibiting the bladder. Pudendal nerve stimulation may be more specific than sacral nerve stimulation for bladder inhibition because fewer side effects, such as leg spasms, were noted.

Future Plans—We plan to evaluate a multichannel implantable simulator for micturition control, bladder stimulation for voiding, and pelvic floor stimulation for preventing incontinence. Such systems have been or are being developed at Case Western University and Rancho Rehabilitation Engineering Center.

Recent Publications Resulting from This Research

- Comparison of Sacral and Pudendal Nerve Stimulation for Bladder Inhibition in the Spinal Cat. Walter JS et al., Soc Neurosci 15:630, 1989.
- Effects of Filling Volume on Detrusor Contractility. Walter JS, in Proceedings of the 11th Annual Urodynamics Society, 11-12, 1989.
- Role of the Urethral Emptying Reflex in High Urethral Resistance Following Spinal Cord Injury. Walter JS et al., in Proceedings of the Thirty-Fifth Annual Meeting of the American Paraplegia Society, 24, 1989.
- Surface Stimulation Techniques for Bladder Management in the Spinal Dog. Walter JS et al., J Urol 141:161-165, 1989.
- Urethral Reflexes in Spinal Cord Injured Cats. Walter JS et al., J Urol 141:569A, 1989.
- Urethral Responses to Sacral Stimulation in the Chronic Spinal Dog. Walter JS et al., Am J Physiol 257:R284-R291, 1989.

[522] Effect of Exercise on Upper Extremity Recovery Following Quadriplegia

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Sponsor: VA Rehabilitation Research and Development Service (Project #B320-2RA)

Purpose—Acute quadriplegia is commonly followed by some recovery of function in one to two spinal segments at the level of the cord injury. For example, a patient with C4 quadriplegia often recovers some C5 function, allowing use of the upper extremities for operating a power wheelchair and for feeding oneself. This upper extremity recovery likely results from several mechanisms, including: 1) resolution of a transient conduction block in descending motor pathways of the spinal cord or in lower motoneurons or roots; 2) motor axon sprouting by spared motoneurons to reinnervate denervated muscle fibers; and, 3) muscle fiber hypertrophy in spared motor units. This study attempts to identify the mechanisms mediating

the various stages of the recovery process and to explore the role of exercise in facilitating these individual recovery mechanisms.

Methodology—Weak upper extremity muscles in patients with recent traumatic quadriplegia are examined using a battery of electrophysiologic tests. One weak muscle is randomly assigned to receive standard twice-daily strengthening; the other weak muscle receives strengthening three times per week. Subsequently, both muscles receive standard twice-daily strengthening. The battery of electrophysiologic tests are repeated monthly to monitor the patterns of recovery and the effects of differential strengthening.

Results/Future Plans—Several distinct types of weakness have been distinguished by comparing compound muscle action potential amplitudes (M amplitudes) as a percent of normal and maximal motor-unit firing rates. Some weak muscles have relatively spared M amplitudes but slow firing rates; others show very low M amplitudes but fast motor-unit firing rates. These findings are consistent with upper and lower motoneuron type weakness respectively. The former is often seen two or more segments rostral or caudal to the cord level, corresponding to the level of a spine fracture in motor-incomplete

quadriplegia. Current work addresses the temporal patterns of recovery and the effects of exercise on this recovery.

Recent Publications Resulting from This Research

Electromyographic Evidence for Motor Axon Sprouting in Recovering Upper Extremities of Acute Quadriplegics. Little JW et al., J Am Para Soc 13:16, 1990.

Patterns of Upper Extremity Weakness and Recovery in Quadriplegia. Little JW, Powers R, Moore D, presented at the Annual Meeting of the American Paraplegia Society, Las Vegas, 1990.

[523] Control of Perioperative Hemodynamic Instability in Quadriplegia

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Sponsor: VA Rehabilitation Research and Development Service (Project #B516-RA)

Purpose—Complete injury to the cervical spinal cord effectively removes all sympathetic outflow from higher centers while parasympathetic control remains largely intact. As the cardiovascular system is highly dependent upon autonomic influences, it is logical that this injury pattern might interface with the complex mechanisms involved in hemodynamic stabilization. We have previously shown that acute cervical injury in man results in a variety of cardiovascular abnormalities, including bradycardia, hypotension, tachyarrhythmias, and cardiac arrest. Fortunately, these autonomic disturbances resolve spontaneously from 2 to 6 weeks after injury via an unknown mechanism. Although this adaptive response is obviously beneficial to the rehabilitative goals of the quadriplegic patient, the chronic stage of cervical spinal cord injury is marked by its own set of cardiovascular abnormalities.

Chief among these is autonomic dysreflexia. This condition, found in more than 85% of quadriplegics, is characterized by transient episodes of profound hypertension, diaphoresis, piloerection, headache, seizures, and even death. To date, the mechanism of this apparent mass sympathetic reflex has not been established, and no satisfactory treatment has been discovered.

During rehabilitation, patients at risk learn proper techniques of bowel and bladder manipulation to minimize the likelihood of triggering a dysreflexic episode. However, the barrage of afferent nervous activity that regularly accompanies surgery represents a potent stimulus of dysreflexia. This phenomenon, combined with

baseline vasodilation and hypotension, makes intraoperative hemodynamic control in quadriplegia extremely difficult. Indeed, systolic arterial pressure swings of over 100 mmHg are commonly encountered during surgery. Surprisingly, there have been no prospective studies published to date that well characterize the magnitude of this problem.

There is considerable controversy as to the ideal anesthetic and pharmacologic approach to take with these individuals. Each technique tried in the past has intrinsic limitations that precludes widespread applicability. On both theoretic and empiric grounds, the transdermal administration of the α -agonist clonidine may effectively blunt both extremes of blood pressure variation during surgery when given prophylactically. Preliminary data from our laboratory strengthen this concept, and support the need for a large scale investigation.

We propose to study this new technique of perioperative hemodynamic control via a randomized, double-blind, placebo-controlled trial. Transdermal clonidine or a matching placebo will be administered to 60 patients with chronic, complete quadriplegia undergoing surgery. Several physiologic parameters will be monitored non-invasively during the procedure to assess autonomic and hemodynamic function, including arterial pressure, electrocardiographic ST segment height, tissue oxygen tension in areas below the level of injury, and sympathetic neurohormonal release. Finally, subjective sensations will be quantitated in awake patients using strictly defined criteria. In addition to intraoperative assessment, blood

pressure and heart rate will be monitored in the immediate postoperative period using a portable measuring device.

The facilities for this research are being provided by the Seattle VA Medical Center: initiation of patient enrollment was in Fall 1990.

[524] Evaluation of Virginia Regional Spinal Cord Injury System Follow-up Care

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this study was to evaluate the follow-up care provided to patients in the Virginia Regional Spinal Cord Injury System (VRSCIS). In the VRSCIS, follow-up care is delivered through three centers to accommodate patients from different geographic areas. Patients may be recalled to clinics at Woodrow Wilson Rehabilitation Center (WWRC), the University of Virginia Medical Center, or to an outreach clinic at Abingdon in Southwest Virginia. In addition, patients may receive a home visit from the WWRC project staff at one and two years after discharge, and at least an annual phone call thereafter.

Methodology/Results—A total of 446 clients in the VRSCIS who met specified criteria were identified as being eligible for inclusion in the study. A representative sample of 200 clients, stratified by geographic region, was randomly selected.

Eligible subjects were contacted by letter inviting their participation in the study. One hundred and forty-three subjects were interviewed to obtain the answers to 12 research questions. The subjects had been discharged from our Center an average of 8.5 years.

Data are currently being analyzed. However, some preliminary findings are as follows: it appears that about 20% of our patients use follow-up care as their primary health care. These patients will initiate follow-up visits rather than wait for contact from the VRSCIS. Forty percent do not have regular follow-up; they elect to wait until something is wrong. This attitude is not particularly surprising in view of the attitude of the general public toward preventive health care.

Pain is an ongoing problem for many people with SCI. Seventy three (51.7%) persons complained of chronic pain. Further, most of these people found that medication did not help. People with incomplete lesions were somewhat more likely to suffer pain. However, this was not statistically significant.

Reimbursement for supplies and durable medical equipment is a major problem for people with SCI. Medicare will, in fact, pay for most supplies but it is extremely difficult to get the information needed to make this happen. Attendant care is difficult to find and most subjects who needed it found paying for it a major problem.

This project was terminated in September 1990.

[525] Pathologic Effects of Recurrent Bacteriuria in Patients with Spinal Cord Dysfunction

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Urinary tract infections (UTIs) are a serious source of morbidity for spinal cord injury (SCI) patients. Recurrent hospitalizations and out-patient services required for treatment of acute and chronic UTIs are extremely expensive and may impede both the rehabilitation process

and vocational pursuits. In addition, UTIs may lead to grave urologic complications and, in some cases, eventual renal failure. There is a need to prevent these infections and their sequelae; this would improve the overall rehabilitation potential and quality of life for SCI patients.

Objectives of this study include: 1) determination of the incidence of clinically significant urinary tract complications coincident with the major bacterial species; 2) determination if aggressive treatment of most pathogenic organisms results in fewer long-term secondary urinary tract complications; 3) determine if patients with certain human leukocyte antigen (HLA) combinations are at unusually high or low risk for developing long-term secondary urinary tract complications; 4) determine if the phagocytic activity of human leukocytes correlates with the incidence of clinically significant UTIs and long-term secondary complications; 5) determine if the degree of bacterial adherence to the urothelium correlates with the incidence of clinically significant UTIs and specific HLA combinations; and, 6) determine the prevalence of *Mycoplasma hominis* and *Ureaplasma urealyticum* in lower and upper urinary tract (where possible in selected patients with SCI), and the association of these organisms with various pathologic conditions, with particular emphasis on upper urinary tract disease and calculi.

Methodology—Records of SCI patients evaluated in the outpatient clinics at Spain Rehabilitation Center are being evaluated to determine the presence of UTI, the species of organisms involved, and type(s) of urologic complications which occur over time. The incidence and severity of urinary tract complications secondary to chronic or repeated infections is documented in successive follow-up visits in a group of SCI patients who are either newly injured or are within 2 years of the initial injury. This group is followed at quarterly intervals and treated aggressively for infection. These patients will be compared to those who are evaluated only once each year.

Also, a group of patients (subjects) who are chronically infected and have diminished renal function, and a

separate group (controls) who have consistently sterile urine or whose sole complicating diagnosis is bacteriuria, have been identified from our patient database. Fifty patients from each of these two groups will have tests performed at the time of their annual urologic evaluation to determine the phagocytic abilities of their peripheral blood neutrophils, the degree of adherence of bacteria to the urinary bladder epithelial cells in those who are infected, and for the determination of HLA haplotypes. Leukocyte phagocytic activity and bacterial adherence will be correlated with incidence of clinically significant urinary tract complications and with particular HLA combinations. Finally, the prevalence of mycoplasma in urine specimens from SCI patients will be determined.

Preliminary Results—Neutrophil phagocytosis assays have been performed on 14 patients from the experimental group, and 11 from the control group, for a total of 25 since August 1988. Numbers are still too small to predict outcomes, although no apparent difference in the phagocytic activity in the two groups has been observed thus far.

HLA antigens have been determined on leukocytes from 23 patients in an attempt to determine whether an association exists between a particular HLA haplotype and predisposition to urologic complications following SCI. The results will be evaluated when a sufficient number of persons have been tested.

Urine screening for mycoplasmas has been performed on 793 specimens with positive cultures identified in 103. Repeated positive cultures over time have been observed in some patients. The distribution of positive cultures, the presence or absence of concomitant bacterial species, and possible clinical implications of these microbiological results are being evaluated.

[526] A Comprehensive Approach to Management of Infertility in Males with Spinal Cord Injury

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Infertility is a major problem among male spinal cord injury (SCI) patients. This study seeks to: 1) determine optimal conditions for producing seminal emission via electrical stimulation of the pelvic sympathetic nerves; 2) compare electrical stimulation with strong vibratory stimulation of the genitalia in eliciting

seminal emission in male SCI patients; 3) determine if repeated stimulation improves semen quality (sperm count, motility, and morphology); 4) determine if intermittent testicular cooling improves semen quality; 5) relate success or failure of seminal emission production to neurologic level and extent of spinal lesion,

urodynamic assessment of lower urinary tract function and incidence of recurrent urinary tract infection; and, 6) artificially inseminate a male SCI patient's female partner who has been unable to be impregnated since the patient's injury.

Methodology—Male SCI patients voluntarily participating in the study will be assigned to a 2 to 3 month trial in the vibratory stimulation group. Seminal emissions will be acquired and sperm counted and examined for viability. Patients failing to produce viable sperm will be entered into the electrical stimulation group if they wish to proceed. Patients who continue to fail to produce adequate numbers of viable sperm will undergo stimulation with testicular cooling. Caffeine stimulation will be performed on selected specimens to evaluate its effectiveness on improving sperm motility.

If these techniques produce no improvement in semen quality, the patient will be given the opportunity to participate in a study of direct aspiration of sperm from the surgically-exposed vas deferens. Viability of sperm produced will be determined. The concomitant success or failure of seminal emission production will be assessed statistically. Female partners of patients with satisfactory sperm production will be evaluated physically and if in good health, artificially inseminated.

Preliminary Results—Twenty-nine patients have been entered in the study. A total of 13 patients have attempted vibratory stimulation techniques. Fourteen patients have undergone electroejaculation. One patient has undergone a vas deferens aspiration of spermatozoa.

Of the 13 patients who have used the vibrator regularly, only two have reported consistent ejaculations. One

of these patients has since had poor success and has not been able to produce an ejaculation for semen analysis. The other patient, identified in the previous progress report as having a normal specimen, was referred to a fertility specialist for evaluation of his spouse and possible insemination trials.

No further progress has been made in improving semen quality using intermittent testicular cooling or caffeine stimulation techniques. Motility continues to be suboptimal for specimens collected during this period.

One specimen has been collected using the vas deferens aspiration technique. The results were somewhat encouraging. This patient underwent 9 trials of electroejaculation. On the first trial, he produced a specimen with a sperm count of 303 million cells/ml with 45% motility and 60% normal cells. Subsequent trials only showed a decrease in sperm quality over a period of approximately one year with the last specimen obtained having no motile sperm. Morphology and count were not reported. A very small specimen (0.2 ml) was collected by vas deferens aspiration. This specimen showed a count of less than one million/ml with motility of 50%. Morphology was not reported. Artificial insemination was attempted using this specimen, but no pregnancy was achieved. To date, artificial insemination has not been attempted using specimens collected by vibratory stimulation. Patient compliance using the vibrator and cooling devices has improved some, but is still poor.

Future Plans—Patients who are unsuccessful with both types of stimulation will be offered the opportunity to participate in a study of direct aspiration of sperm from the surgically-exposed proximal vas deferens.

[527] Medical and Psychological Considerations Regarding the Surgical or Pharmacological Treatment of Impotence in Males with Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Erectile dysfunction is prevalent in the spinal cord injury (SCI) populations as well as in other males with various forms of spinal cord dysfunction. For the last 15 years, various penile implants have been developed and utilized for erectile dysfunction; recently, pharmacological interventions have become available as well. Much of the existing literature concerning both of these procedures,

particularly as it relates to SCI, has been focused on medical and/or physical complications, with very little attention paid to the impact of these procedures on sexual behavior, sexual satisfaction and/or relationships. This study will prospectively evaluate the impact of both implant and injection procedures on sexual behavior, sexual satisfaction, and relationships in the SCI population.

Methodology—All couples are screened for evidence of relationship stability and desire to comply with the study protocol. In addition, they are assessed for psychological and physical health, including evidence of drug and/or alcohol abuse, prominent depression, and marital discord. Individuals showing evidence of any of these problems are referred to appropriate counseling or other treatment before beginning either the implant or injection procedure.

Once screening has been completed, the couple is assigned on a randomized basis to either the immediate treatment or delayed treatment group. Those in the immediate treatment group complete a battery of sexual behavior and satisfaction scales before the intervention (implant or injection) is initiated. Three months after the procedure has been completed, the couple repeats the same battery of forms.

In the delayed treatment group, a similar sequence occurs, except the battery is given 3 months prior to the intervention, and is followed with a second administration of the battery immediately prior to intervention. The battery is administered a third time 3 months post-intervention. This sequence of tests controls for spontaneous changes in sexual behavior and/or satisfaction which may occur simply as a function of time or idiosyncratic events.

Preliminary Results—Over the past grant year we identified, on average, two potential participants per month. However, many of these persons are excluded from the study for various reasons, including: 1) the absence of a

regular partner; 2) inadequate reading ability; and, 3) poor physical and/or emotional health. Only a few candidates who have agreed to an implant or injection have refused to participate.

To date, eight couples have completed the immediate intervention protocol, and three more are in the process of completing it. Four couples have completed the delayed intervention, and one more has yet to complete the study. Unfortunately, several couples have dropped out of this group: two couples ended their relationship during the course of the study and two participants experienced complications from the injection procedure.

We have advertised the availability of this screening process and study in our consumer newsletter, *Pushin' On*, and anticipate a continuing supply of potential candidates. Very preliminary results suggest that these interventions do not appear to make a major impact on sexual behaviors and/or frequency, but sexual self-esteem scales do seem to reflect improvement, more for SCI males than for their partners.

Future Plans—We will continue to recruit SCI men and their partners for both the implant and injection treatments and collect data from participants pre- and post-treatment.

Recent Publications Resulting from This Research

- Sexual and Marital Satisfaction Following Penile Implant/Injection. Jaworski TA, Richards JS, Lloyd LK, ASIA Abstracts Digest 15:114, 1989.
- Intracavenous Injection for Management of Erectile Dysfunction in Spinal Cord Injury. Paraplegia (accepted for publication).

[528] Influence of Age on Rehabilitation Outcome of Persons with Spinal Cord Injury

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—As the median age of the U.S. population has increased, special attention is now being given to the health care needs of older persons. Even though most people with spinal cord injury (SCI) are relatively young, the health care needs of the subpopulation of older people with SCI may vary enough from their younger counterparts to suggest a need for alternative treatment modalities.

The purpose of this study is twofold: Phase I will examine the influence of age at the time of SCI on various

demographic, process-oriented, and short-term outcome factors. Phase II will examine the longer-term impact on the health care delivery system of an aging population with SCI.

Methodology—All patients enrolled in the National SCI database will be included in this study. During Phase I, all patients will be divided into six age groups in 15-year intervals. Demographic, process-oriented, and short-term outcome factors will be compared for each age

group, either by calculating the percentage of patients with each factor in each age group and then using the Chi-square test, or by calculating the arithmetic mean for each variable in each age group and then using Student's *t*-test. Multivariate techniques, such as analysis of variance, multiple linear, and logistic regression will be used to control for the possible confounding effects of appropriate covariates such as neurologic level and extent of lesion.

Phase II will be a cross-sectional study comparing current age with outcomes during the current follow-up year. The data will be analyzed in essentially the same manner as in Phase I.

Preliminary Results—The Phase I data set has been created and includes 12,418 patients. Preliminary findings show that patients in the oldest age group are most likely to be white females with motor functional quadriplegia whose injuries resulted from falls. More than one-third

were widowed, slightly over one-half were high school graduates, and very few were still employed in the competitive labor market at the time of their injury. These findings were all highly statistically significant ($p < 0.0001$). There was also a statistically significant decrease in both the mean days from injury to system admission, and the mean total days hospitalized for patients in the oldest age group relative to all other age groups ($p < 0.001$). Patients in the oldest age group were also far more likely to be discharged to nursing homes and to be ventilator-dependent at discharge than their younger counterparts ($p < 0.0001$). In addition, patients in this age group are the least likely to improve neurologically. Not surprisingly, few patients are employed 2 years post-injury.

Future Plans—All Phase I activities have been completed. Completion of Phase II and dissemination activities are underway.

[529] Ultrasound for Urinary Tract Surveillance of Persons with Spinal Cord Injury

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Purpose—Since renal ultrasound examinations (RUSE) are easily performed, completely noninvasive, well-tolerated, and relatively inexpensive, RUSE could prove to be an ideal method for the periodic routine long-term surveillance of the upper urinary tract. This surveillance would help considerably in detecting and managing some of the most serious secondary complications of SCI.

This study seeks to: 1) determine the role of RUSE in the periodic routine long-term upper urinary tract surveillance of persons with SCI; 2) determine whether RUSE of the upper urinary tract is sufficiently sensitive to detect abnormalities identified by excretory urography (EXU) or comprehensive renal scintigraphy (CRSP); and, 3) determine in what instances RUSE could be substituted for either EXU or CRSP in the routine screening for secondary urologic complications among persons with SCI.

Methodology—Investigators have previously shown the utility of CRSP for long-term urinary tract screening in lieu of the more traditional EXU and serum creatinine or creatinine clearance. Building on that experience and other recent studies of ultrasound, this project will compare the results of RUSE with those obtained via EXU and CRSP for approximately 200 persons with SCI. In most instances, the tests will be performed on the same day, and in no instances will they be performed more than two weeks apart.

Progress—The study began June 1, 1990. Data collection has begun. First year efforts will concentrate on the development of data collection instruments and an accompanying syllabus. CRSP, EXU, and RUSE will be performed and evaluated.

[530] A Clinically-Derived Protocol for Changing Condom Catheters in Males with Spinal Cord Injury

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Purpose—While meticulous hygiene and observation of the condom catheter and penis is consistently advocated, a disagreement exists on how often the condom catheter needs to be routinely changed. Recommendations range from changing it twice a day to changing it every few days. In fact, several of the most highly regarded nursing texts make no recommendation on how frequently it should be changed. Failure to reach a consensus on this issue is undoubtedly the result of the lack of any meaningful data upon which to base this clinically important decision.

The objectives of this randomized controlled clinical trial are: 1) to determine the incidence of urinary tract and penile skin complications for male patients with spinal cord injury (SCI) whose condom catheters are changed daily, every other day, or every third day; and, 2) to develop a protocol for routine changing of those catheters.

Methodology—The study population will include all male patients with SCI admitted to our hospital who use condom catheter urinary collection devices, are asymptomatic for urinary tract infection for at least 48 hours, and are free from other urinary tract and penile skin complications at the time of entry into the study.

Subjects will be randomly assigned to one of three groups: 1) patients whose condom catheters are changed

every day (Group I); 2) changed every other day (Group II); and, 3) every third day (Group III). Routine inspection of the penile skin will occur whenever the catheter is changed regardless of study group assignment. Total study population will be 87 patients. The duration of the study will be 30 days for each patient. A single brand of condom catheter has been selected and will be used for all study subjects. Patients having numerous accidents related to an improperly fitting catheter will be dropped from the study. At the conclusion of the study, a protocol will be developed for routine changing of these catheters.

Preliminary Results—During the past year, there has been a continuing problem in obtaining patients to be study subjects, the 30-day time factor being the major obstacle (many patients are discharged before they can complete the study). It was decided to delete the third study group and include only patients in the first two groups. In addition, to increase the sample size, patients from the SCI outpatient department will be included. The nurse clinician in the clinic will assess dependability and obtain patient consent to participate. Currently, 14 patients have participated in the inpatient component of the study.

Future Plans—Plans are to continue enrolling patients.

[531] Histopathology of Denervated Skin Following Spinal Cord Injury

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Purpose—Skin complications represent a leading source of morbidity in the spinal cord injured population, yet relatively little is known about the histopathology of denervated skin. In order to improve the clinical management of these complications, and ultimately to prevent them, we are conducting a study to increase the understanding of precisely what happens at the cellular and tissue level when the body's largest organ, the skin, is denervated.

The objectives of this study are to: 1) describe and establish the histopathology of denervated skin in patients with spinal cord injury (SCI) using appropriate laboratory and electron-microscopic techniques; 2) establish the pathogenesis and natural history of skin changes following SCI; 3) determine the nature of the relationship between the neurologic level and extent of SCI and the occurrence of specific skin changes; and, 4) determine whether there is a meaningful correlation between the

severity of post-SCI skin complications and possible covariates such as the histopathologic changes observed, the neurologic level, and extent of lesion.

Methodology—Skin punch biopsies are obtained from patients with SCI who have injuries that are neurologically complete, sensory sparing only, or motor nonfunctional. Study patients are divided into three groups by level of injury; 1) T6 and above; 2) T7-T11 with sacral reflexes present and upper motor neuron evidence to legs; and, 3) T12 and below with absence of sacral reflexes and lower motor neuron loss to legs. Biopsy specimens are obtained from a group of patients who have chronic SCI, more than one year post-injury, as well as a prospective group of patients who were injured less than two months prior to the time the skin biopsy was obtained. Skin biopsies will be examined by a dermatopathologist using histopathologic methods of examination. In addition, a subset of the biopsies will be studied by electron microscopy.

Preliminary Results—Considerable time is required to review records and select patients who are appropriate to the study. Consent must also be obtained, a sometimes difficult task in the prospective group of patients when it is explained that a second biopsy will be required in 2 years. The prospective study has almost been completed (Groups 2 and 3 need two more patients each). It is extremely difficult to find complete injuries in these categories. The electron microscopy study has had all the specimens collected and findings are being summarized. Since this is a controlled study, the dermatopathologist is blinded; however, the principal investigator received the reports. Some preliminary analyses of the findings will be initiated later in this project year.

Future Plans—Studies of biopsy specimens in the chronic group will continue. We will also start to evaluate early results from these biopsy specimens to see if the histopathologic findings are related to the level of injury.

[532] Natural History and Clinical Course of Skin Complications (Excluding Pressure Ulcers) in Persons with Spinal Cord Injury

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Purpose—Persons with spinal cord injury (SCI) frequently develop an array of potentially serious skin complications in addition to the more dramatic pressure ulcer typically associated with spinal paralysis. Examples include superficial and deep bacterial and/or fungal infections, furuncles, abscesses, dermal fibrosis, paronychia, and a host of related changes affecting the nail plate, bed, and wall. Our experience is that nonpressure ulcer skin complications represent a more significant and serious source of morbidity in this population than generally acknowledged.

The objectives of this study are to: 1) establish a clinically useful method to document the occurrence, etiology, definitive characteristics, management, and treatment outcome(s) of all nonpressure ulcer skin lesions occurring in a series of patients with SCI; 2) determine the nature of the relationship(s), if any, between nonpressure ulcer skin lesions in patients with SCI and specific characteristics of the spinal injury itself (e.g., neurologic level and extent of lesion, time post-injury, etc.); and, 3) develop, print, and distribute a clinically-oriented, teaching/training monograph devoted

to the photographic documentation and description of nonpressure ulcer skin lesions in patients with SCI.

Methodology—A data collection instrument has been developed, refined, and field-tested to document nonpressure ulcer skin complications in patients with SCI. A history is obtained and a physical examination is performed at the patient's annual follow-up examination. A clinical nurse specialist examines the patient's skin and completes the data collection forms. Data are obtained by actual observation of the patient. When possible, a diagnosis of the skin lesion(s) is made. Skin lesions are documented by photographs. When appropriate, bacterial and/or fungal cultures are acquired and appropriate treatment is given.

The analysis will be stratified by potential risk factors such as neurologic level and extent of lesion, age group, sex, and time post-injury. A high quality, clinically-oriented monograph will be produced by the project team.

Preliminary Results—Data have been collected on 360 patient visits. Fifty-two patients were seen at two successive

annual visits so that there are now 308 patients total. These numbers are fairly close to the projected number of patients to be studied. The compliance meter which was used initially to obtain a more objective measure of the amount of skin thickening was discontinued. After a thorough evaluation of the measurements using the compliance meter and comparing those measurements to the clinical assessment of skin thickening, it became obvious that the correlation was very poor; of even more concern was the fact that the compliance meter did not give consistent readings in the same subjects.

We are continuing to take photographs of interesting skin lesions which may be used for the monograph at the end of the study.

It is still too early to analyze the data in depth. However, we are starting to look at trends in the data, especially the clinical grades of dermal thickening.

Future Plans—The goal is to obtain data on 250 to 400 patients annually. As additional data become available, preliminary analyses will be made to evaluate the progress of the study.

[533] Natural History and Clinical Course of Urinary Tract Complications in Patients with Spinal Cord Dysfunction

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Appropriate clinical management of patients with neurogenic bladders resulting from spinal cord dysfunction requires: 1) knowledge of the natural history or clinical course of urinary tract complications in this group; and, 2) data from which to determine if urinary complications in this group are predictable from early post injury urinary tract status and method of early bladder drainage management. The objectives of this study include: 1) to document the natural history and clinical course of urinary tract complications in persons with spinal cord injury (SCI) by continuing to build a urology database; 2) to answer specific research questions addressing the effects of *a*) various bladder drainage management methods; *b*) various bacterial pathogens; and, *c*) various demographic factors (including age, sex, etc.) on long-term renal function, measured by effective renal plasma flow (ERPF), and the development of urologic complications including orchitis and/or epididymitis, penoscrotal abscess, penoscrotal fistula, ureterectasis, pyelocaliectasis, and calculi in a population with SCI; and, 3) to develop, refine, and offer for extramural acquisition a transportable urologic complication data collection protocol and its associated database. One of the specific research questions is addressed: "What is the incidence of clinically significant urologic complications in females with spinal cord injury?"

Methodology—Data are collected for each patient admitted to the University of Alabama—Spinal Cord Injury Care System (UAB-SCICS) at admission, discharge, and

annually thereafter. In addition, data have been collected retrospectively on 596 patients admitted to the UAB-SCICS between 1970 and 1979; prospective data are collected on these patients as they return for their annual follow-up examinations.

In our study of the incidence of urologic complications in females, patients were stratified by known risk factors (including method of bladder drainage management and neurologic level, and extent of lesion). The incidence of each urologic complication was then calculated for both females and males.

Preliminary Results—Complete studies have been performed and data recorded on 327 patients from a retrospective study group and 876 patients from a prospective group, thus yielding 1,203 completed studies to date.

In a study of 110 females injured between 1973 and 1985, multiple linear regression was used to assess the effects of neurologic classification method of bladder management and renal complications on renal functions at discharge and up to 10 years post-injury. However, bladder management methods and neurologic classification showed no statistically significant effect on renal function. Conclusively, the method of bladder management in females does not adversely effect long-term renal function.

A second study compared 42 females with 186 males injured between 1973 and 1984 according to age, race, neurologic level and extent of lesion, method of bladder management, and incidence of secondary urologic

complications during the first 4 years post-injury. No statistically significant differences between males and females were found when multivariate statistical techniques were used to control for the possible confounding effects of age, race, bladder drainage management, neurologic level and extent of lesion.

Future Plans—Five additional research questions have been included: 1) What are the effects of various bladder drainage management methods on long-term renal func-

tion in persons with SCI? 2) When are persons with SCI at greatest risk for developing clinically significant urologic complications? 3) What is the optimal schedule for routine urologic follow-up of persons who have experienced a spinal cord injury? 4) What is the effect of external sphincterotomy on long-term urologic function in persons with spinal cord injury? and, 5) Are the consequences of renal calculi more serious in older than younger persons with SCI? The first question will be addressed during the next year.

[534] Disuse Osteoporosis in Spinal Cord Injured Patients

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Purpose—Our research project had three goals: 1) to describe the natural history of bone loss with acute paralysis in newly injured spinal cord injured patients; 2) to assess the degree of osteoporosis and associated fracture risk in patients with spinal cord injury of long duration; and 3) to examine the efficacy of two intervention modalities, functional electric stimulation (FES), and upright stance on a tilt table, to prevent or reverse bone loss.

Progress/Methodology—We studied 30 newly injured patients prospectively for up to 2 years postinjury. The chronic response was investigated in a retrospective study of individuals with duration of injury between 1 and 33 years. Data collection included bone mineral density measurements of the lumbar spine and proximal femur (by dual photon absorptiometry), and biochemical assays of bone metabolism. The two studies are considered together as representing the early and later stages of a continuum of responses.

Results—Different responses were observed in the proximal femur than in the spine. In the femur, where mechanical loads had been greatly reduced or eliminated, the immediate response to acute paralysis was increased bone remodeling resulting in rapid loss. The rate of bone loss was approximately 1% per month, with an indication of more rapid loss in the first 4 to 5 months (2.1%), and slower loss thereafter (0.9%). Bone turnover was elevated above normal, and increases were observed in both resorption and formation markers, presumably, with resorption rate greater than formation.

With chronic paralysis, there appeared to be a stabilization of this response. This is reflected both by normal levels of metabolic markers, and no evidence of continued loss over time (that is, lack of correlation between duration of paralysis and bone mass). However, mean femoral bone mass in this group was decreased below predicted normal values by 28%.

The specificity of this response was examined in a study of 21 polio survivors who had different levels of ambulation, and differing lower extremity muscle strength. Subjects were grouped by ambulation type: wheelchair use, ambulation with assistive device or abnormal gait, and normal ambulation. Mean femur bone mineral density of all subjects (not grouped) was significantly below predicted normal values (92%). However, if subjects were separated by ambulation status, the normally ambulating subjects were not different from predicted normal values (101%), while those who used assistive devices and those who used wheelchairs had femur bone mineral density significantly below normal (84% and 83%, respectively). There was no significant difference between these latter mean values. This may be due to several factors, such as: several wheelchair users were semi-ambulant and/or recently in wheelchairs, others had variable muscle strength and distribution of paralysis/paresis regardless of whether they were able to ambulate.

No decline was observed in the lumbar spine either with acute or chronic paralysis. It is suggested that weight-bearing of the upper body during sitting provides sufficient loading of the vertebrae to maintain skeletal integrity.

Studies of two intervention modalities were initiated. Six subjects participated in a study of the application of FES to the quadriceps femoris muscle, 3 times per week, 50-60 minutes per session, over 8 months. No significant changes were observed in either muscle strength (while stimulated) or bone mineral density. The lack of response may be due to several factors. The duration of injury for all subjects was greater than 2 years (and up to 25 years), so that they may have had a reduced physiological capacity to respond to the treatment, and the stimulation parameters may have been inadequate (100 milliamps, surface electrodes). We were unable to complete the study of upright stance because of low recruitment and poor compliance among participants.

Implications—The results indicate that the skeleton responds rapidly and locally to immobilization, but that

this response may stabilize within a few years after the injury. We were unable to demonstrate a response to electrical stimulation in patients with chronic spinal cord injury. The implication of these data, taken together, is that therapeutic modalities (such as medications to suppress bone loss or physical interventions) should begin within the first year in order to maximize effectiveness.

Recent Publications Resulting from This Research

- Effects of Chronic Immobilization (Paralysis) on Vertebral and Femoral Bone Mineral Density. Kiratli BJ, Agre JC, Smith EL, J Bone Miner Res 4:S173, 1989.
Femoral Bone Mineral Density in Polio Survivors. Kiratli BJ et al., Arch Phys Med Rehabil 70:A16, 1989.
Reduction in Femoral Neck Strength with Disuse. Kiratli BJ et al., Am J Phys Anthropol 81:251, 1990.

[535] Standard Versus Low Molecular Weight Heparin in the Prevention of Thromboembolism in Spinal Cord Injury

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Purpose—The purpose of this study is to determine whether LMW (Logiparin) is as safe and effective as standard heparin in the prevention of thromboembolism in patients with complete motor paralysis due to spinal cord injury (SCI).

Methodology—After informed consent is obtained, patients are randomized within 72 hours of injury to receive either Logiparin, 3500 u subcutaneously once daily; or standard heparin, 5000 u subcutaneously every 8 hours for an 8-week period. Activated partial thromboplastin times, platelet counts, hemoglobin, and hematocrit are obtained at baseline and twice weekly. Venous flow studies, including impedance plethysmography, Doppler examination, and in selected cases compression ultrasound, are obtained at baseline and twice weekly for the first 2 weeks, once weekly for the next 2 weeks, and biweekly for the last 4 weeks. Positive results on venous flow studies are confirmed with venography. The study is discontinued if a patient has a thromboembolic event or bleeds.

Results—In the first part of this investigation, 41 consecutive patients were randomized within 72 hours of

injury to receive either Logiparin or standard heparin. The age, sex distribution, location of spinal injury, and baseline activated partial thromboplastin time were very similar for both groups. Of the 20 patients randomized to Logiparin, 16 completed the 8 weeks without incident. Two were transferred to other institutions 4 to 29 days after initiation of therapy; none of these patients experienced thrombosis or bleeding. An additional two patients had to be switched to standard heparin at day 22 and 23 because of a temporary shortage of the Logiparin. None of the low molecular weight heparin-treated patients had thrombosis or bleeding (95% confidence interval, 0% to 14%).

Of the 21 patients randomized to standard heparin, 7 experienced bleeding or thrombotic events, giving a cumulative event rate of 34.7% (95% confidence interval, 13.7% to 55.2%). Two patients had bleeding severe enough to require discontinuation of the heparin; in both, the activated partial thromboplastin time was considerably prolonged. Three patients had deep vein thrombosis documented by abnormal venous flow studies; in two, the diagnosis was confirmed by venography, and in the third, the flow study 5 days earlier had been normal and at the time of the abnormal flow study the affected leg was

swollen. This patient was treated with full-dose anticoagulation and a follow-up flow study showed resolution of the thrombus. Two patients, aged 22 and 52, suddenly expired while being turned in bed on days 38 and 21 after admission. Both had been considered to be making excellent progress and had no other medical illness. In both patients, post-mortem diagnosis was massive pulmonary embolism. The remaining 12 patients completed the 8 weeks without incident.

None of the patients on Logiparin had a hemorrhage or thrombosis, whereas seven subjects assigned to stan-

dard heparin had such events. This difference in event rate is statistically significant ($p=0.006$). Examining the frequency of thrombosis alone also yielded a significant difference ($p=0.020$). Because there was a statistically significant increase in event rate in the standard heparin group, and because two patients in this group had fatal thrombosis, the trial was terminated.

Recent Publications Resulting from This Research

Low Molecular Weight Heparin in the Prevention of Thromboembolism After Spinal Cord Injury. Green D et al., Ann Intern Med (in press).

[536] Managing Urinary Tract Infection in Spinal Cord Injury

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—In this project we are investigating the techniques and procedures that will improve the prevention and treatment of urinary tract infection. Our objectives are to: 1) increase patient involvement and responsibility in monitoring, prevention, and management of urinary tract infection; 2) develop a systematic approach in identifying the presence of infection, localizing the site of infection, and controlling the infection with simple steps; and, 3) identify a safe management method for resistant bacteriuria.

Methodology—*Self-monitoring bacteriuria at home.* The Dip-Slide method used in this project to detect the presence or absence of bacteriuria appeared to be easy for the patients to learn and perform. Before discharge, patients were instructed in the procedure for using Dip-Slides, followed by an actual performance of the test and interpretation of the results by the patient. With this technique, the Dip-Slide with culture medium on each side was dipped into a fresh urine specimen, then placed in a warm location for 24 hours. The test results were incorporated into the bladder management at the first outpatient visit. The colonies that grew on the Dip-Slide were easily identified. Patients had no difficulty determining the colony density on the Dip-Slide. It is an effective, convenient, and less expensive screening procedure for home use. Once able to monitor bacteriuria, the patient was instructed in the proper steps to take when asymptomatic bacteriuria is found. Emphasis was placed on the need to increase the frequency of bladder emptying.

Progress/Preliminary Results—There are 35 patients participating in the study. Seven of the 35 did not perform the assigned testing at home. The seven indicated that the main reason for not performing the self-monitoring was that there were too many things to do after discharge. More than half of the studied patients indicated interest in continuing the test for self-monitoring. Six patients had significant bacteriuria, and 12 had sterile urine culture as detected by the Dip-Slide method.

Localizing the site of urinary infection prior to antibacterial therapy. In a previous study, we found that the Fairley Bladder Washout test could be simplified for use as a clinical screening procedure to localize the site of infection and sometimes achieve therapeutic results.

The total number of patients involved is now 28. Among the 20 patients who had bladder irrigation with diluted Betadine solution (30 ml), 4 patients experienced bladder spasm. Of all the patients tested, half achieved complete or near-complete bladder preparation in that the post-irrigation specimen had none or few colonies in the Dip-Slide. Preliminary results indicated that one-third (10) of the 28 subjects appeared to have a lower tract infection, 8 appeared to have an upper tract infection, and the rest were indeterminate.

Managing lower tract infection with resistant organisms. To date, three patients have been studied. All patients have shown conversion of a highly resistant organism to a different organism. One converted to a different highly resistant organism, one converted to a highly sensitive organism, and the other had sterile urine after irrigation procedures.

[537] Expiratory Muscle Training in Spinal Cord Injury: A Randomized Controlled Clinical Trial

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This study has been designed to determine whether a simple expiratory muscle training program will be effective in improving expiratory force, increasing endurance, and reducing complications in individuals with spinal cord injury (SCI).

Methodology—Approximately 60 patients who have had a cervical or upper thoracic SCI no longer than 6 months prior to evaluation and who meet study criteria are to be studied. At initial evaluation, the patient undergoes a comprehensive medical history, physical examination, and pulmonary function testing. Each patient is instructed in the proper use of an expiratory resistive breathing training device, through which the patient performs 10 expiratory maneuvers twice a day, for 30 days. Patients are monitored by physician-investigators while performing the expiratory maneuvers. Patients are randomly assigned into one of two groups: 1) the Expiratory Training Group which performs the program with a closed-end resistive breathing device; and, 2) the Control Group

which uses the device with an open gauge without respiratory resistance. At the end of 30 days of respiratory muscle training, each patient undergoes an exit evaluation of history, physical exam, and pulmonary function testing. The same procedure is performed at follow-up. Comparisons of results between training groups and between time periods is then conducted.

Progress—Twenty-seven SCI patients have completed their participation in the project, and five are actively involved with the clinical trial. Of the total 32 subjects, 9 underwent initial clinical and pulmonary function testing and then withdrew from the study. The remaining 23 subjects consist of 14 patients randomized to the Expiratory Resistance Training Group (including 1 currently enrolled) and 9 randomized to the Control Training Group (including 4 currently enrolled). Additional subject recruitment and data collection are planned. Preliminary data analysis is in progress and preparation for presentation of the technique and preliminary data is underway.

[538] Treatment of Spasticity with Electrical Stimulation in Spinal Cord Injured Men and Women

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Spasticity, common in spinal cord injury (SCI), frequently interferes with an individual's work, sleep, self-care, and recreational activities, and can contribute to increased morbidity. Fertility studies at the National Rehabilitation Hospital have shown that SCI men receiving rectal probe electrostimulation (RPES) for ejaculation experience significant improvement in their spasticity for up to 6 or 8 hours and occasionally longer. This 3-year study will determine the technical factors associated with modifying spasticity and what subject characteristics affect the ability to modify spasticity using RPES.

Methodology—During the first year, 10 healthy SCI men will be tested twice a month. The testing includes assessment of subjects' spasticity before RPES and day-long monitoring by an independent team of assessors. Subjects are also asked to rate any changes in their spasticity and performance of self-care activities. The study will include five additional SCI men and five SCI women in both the second and third years. Data will be analyzed to determine what factors most strongly modify spasticity.

Implications—RPES may become an effective alternative to other modalities, which often have undesirable side effects.

Recent Publications Resulting from This Research

The Effects on Spasticity of Rectal Probe Electrostimulation.
Halstead LS, Seager SWJ, in Proceedings of the American
Spinal Injury Association, 1989.

[539] Voice-Augmented Telephone Access for Quadriplegics

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Sponsor: *National Institute of Child Health and Human Development, National Institutes of Health*

Purpose—Spinal cord injury causes dramatic changes in a person's ability to function in society. With proper rehabilitation, many paraplegics and some quadriplegics are able to live and function with a high degree of independence. Those with C-5 and above paralysis currently must depend on family, medical

personnel, and a variety of assistive devices to accomplish the most basic activities of daily life. This project proposes to use automatic speech recognition to enhance telephone use by quadriplegics. It also proposes to examine use of the same system for note-taking and note retrieval.

[540] Treatment of Infertility Among Spinal Cord Injured Males Using Vibratory Stimulation

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The objective of this project is to evaluate serial changes in hormonal levels, semen analysis findings, and clinical course using repeated vibratory stimulation of the penis in spinal cord injured (SCI) men. By determining relationships between external stimulation, serial hormonal changes, and serial semen analysis results, this study is expected to provide new insights into mechanisms of infertility and their management in SCI patients.

Methodology—Twenty-five male patients between the ages of 18 and 45 years with acute traumatic SCI of 6 months duration or longer and no associated injury or illness who agree to participate, and their partners will be studied. Following a detailed explanation of procedures, risks, and benefits, informed consent is

obtained from each patient. Strict confidentiality is maintained.

Progress—A consent form has been developed and revised, and Institutional Review Board approval obtained. The actual procedure for vibratory stimulation was developed. Pilot information was obtained from several patients concerning the use of vibratory stimulation. The procedures were refined by the Northwestern Memorial Hospital Reproductive Endocrinology Laboratory and the Andrology Laboratory, where hormone and semen studies, respectively, will be performed.

To date, one subject with high thoracic paraplegia has given informed consent, been formally enrolled, undergone vibratory stimulation, and is actively participating in the project. Additional data collection is planned.

[541] Neuromuscular Plasticity: Recovery After Spinalization

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—Our emphasis is on the plasticity of the neuromuscular system in response to spinal lesions and the consequences of the plasticity or lack of it, to locomotor capabilities.

Methodology—The experimental models to be used in addition to normal cats are: low thoracic complete spinalization, surgical isolation of the lumbar cord, partial deafferentation, partial denervation of muscle, self-reinnervation of muscle, and surgical removal of synergistic muscles. Variations of these models include three forms of training, passive hindlimb oscillation and static posture maintenance of spinalized cats, and hindlimb oscillation of spinally isolated cats. The plasticity of

movement control will be studied at the systemic level by carefully assessing force, velocity, length, and electromyographic pattern of individual muscles. Cellular responses of and within motor units and of muscles, will be studied in an effort to define mechanisms that might play a role in the induction of the neuromuscular adaptations.

Implications—These studies should provide further data suggesting that the clinical benefits of optimizing post-neural lesion care can be significant. Further, these studies should provide important data which identifies the features of the rehabilitation procedures that are particularly effective.

[542] Movement Deficits Following Spinal Cord Lesions (Macaques)

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Purpose—Motor disorders have long been known to follow damage to the dorsal columns. However, following extensive postoperative training, the only enduring deficits are those involving the grasping and manipulation of objects with the fingers. These results have indicated that the dorsal columns provide specialized sensory information that is critical to the execution of the precise finger movements involved in active touch. As a source of feedback to the motor cortex, the dorsal columns may provide information that is critical for digital fractionation, involving precisely timed and directed sequences of movement of individual digits.

Methodology—The proposed experiments test this hypothesis with a methodology that permits direct challenges and measurements of digital motor acts. We have developed two paradigms which evaluate the ability of monkeys to make independent finger movements or track moving stimuli with the finger. The experiments will evaluate in detail the deficits in individual finger movements that result from DC lesions, and the animals will be retrained to maximal capacity with specialized

shaping procedures. The contributions of separate populations of joint and cutaneous receptors to digital fractionation and tracking will be evaluated, and the role of dorsolateral sensory pathways in recovery of digital dexterity will be determined. Because the corticospinal pathway is regarded as the afferent pathway of control over motoneurons involved in digital fractionation of primates, the consequences of dorsal column and corticospinal tract section will be compared directly.

Results—We have previously demonstrated that many of the initially debilitating motor effects of DC lesions recover with training. Fine movements of the hands have been an exception to this, but training procedures are critically important for providing full opportunity for recovery. The stepwise shaping procedures for the finger movement tasks are appropriate to test the limits of functional plasticity of the spinal cord following well-defined damage.

Implications—A major goal of this work is to provide information of direct relevance to clinical neurology and

neurosurgery. A better understanding of spinal tract function is fundamental for accurate diagnosis of central nervous system pathology affecting the somatosensory system. Also, an accurate description of the functional

contributions of the different spinal inputs to these regions is fundamental to an understanding of somatosensory coding mechanisms at thalamic and cortical levels.

[543] Fundamental Studies in Spinal Cord Injury

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Purpose/Methodology—In order to provide a scientific basis for a possible therapeutic approach to human spinal cord injury, animal (rat) trials are being conducted with multiple classifications of agents, including calcium-entry blockers, steroids, hyperbaric oxygen, and antioxidants. In addition, therapeutic trials with phosphate and other buffers will be continued. Therapeutic trials will, at the same time, test various hypotheses concerning primary and secondary injury factors in the production of necrosis following traumatic injury. These include calcium toxicity, ischemia, and free radical injury. Lactic acid myelopathy *in vivo* that developed earlier will be evaluated, using pH electrodes and a chemical microsensor, to

determine the extracellular pHs in the spinal cord required to produce myelopathic changes. Studies will be completed that were previously initiated on secondary changes in the rat spinal cord following Wallerian degeneration and postmortem autolysis, which are being compared with the primary traumatic events, and are critical to the interpretation of the latter.

Future Plans—Future studies are anticipated which will determine the role of calcium in these secondary events which are present in the traumatized spinal cord. In addition, freeze-fracture membrane pathological evaluation of spinal cord trauma will be initiated.

[544] Clinical Research Center for Acute Spinal Cord Injuries

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Purpose—This proposal is for a continuation of the Clinical Research Center for Acute Spinal Cord Injuries at New York University. The underlying theme of this proposal is to intensively study experimental spinal cord injury at a basic pathophysiologic level as a model for clinical spinal cord injury. Major emphasis will be placed on studying the effects of trauma to the spinal cord beyond the acute period following the injury.

Methodology—Changes in the distribution of ions (such as calcium, sodium, and potassium) within the cord, neurophysiologic studies of ascending and descending pathways, and the role of cellular inflammatory response as a cause of progressive damage to the spinal cord in the weeks following the trauma, will be used to test the hypothesis that the injury to the spinal cord is progressive beyond the first 12-24 hours. This will provide important

information about treatment regimens which may have to be utilized for extended periods if any recovery is to be achieved. In addition to determining these pathophysiologic changes in the spinal cord, the effect of different treatment modalities on these parameters will be tested.

The clinical studies will examine the efficacy of opioid antagonists and corticosteroids in the amelioration of spinal cord injury as part of a multi-center randomized trial. Alternate therapies will also be tested in pilot studies. Experimental treatment will test the hypothesis that the opioid receptors play a role in spinal cord injury and that this therapy and corticosteroids are effective even when administered more than 1 hour after injury. The evaluation of therapy on the recovery of injured animals will include neurologic, physiologic, and morphologic outcome parameters. This will provide a

comprehensive picture of the experimentally injured spinal cord and the response to therapy that will provide a rational basis for selecting clinical therapies.

Implications—The goal of a Center for Spinal Cord Injury will be realized by the close integration of the component projects of this proposal.

[545] Evaluation of Neural Implantation for Recovery from Spinal Injury

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Purpose/Methodology—The object of this project is to use implanted neural tissue and cells to facilitate functional recovery after contusion injury to the spinal cord. Survival of implants and integration of the implants into host tissue will be investigated at set intervals using light

and electron microscopy and immunocytochemistry. Behavioral deficits resulting from spinal cord contusion and changes to these parameters due to tissue implant will be regularly assessed. All evaluations will include both acute and chronic preparations.

[546] Microstimulation of the Sacral Spinal Cord

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Purpose—The objective of this research is to determine the feasibility of using microstimulation of the sacral spinal cord with arrays of ultraminiature electrodes to restore control of genito-urinary functions in individuals with spinal cord lesions.

Preliminary Results—The location of cell bodies of external urethral sphincter neurons and terminal connections of penile afferents in the sacral spinal cord have been determined in the cat.

[547] Microstimulation of the Sacral Spinal Cord

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Sponsor: *National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Purpose—The objective of this research is to determine the feasibility of utilizing microstimulation of the sacral spinal cord as part of a neural prosthesis for controlling micturition and sexual function in spinal cord injury victims.

sacral spinal cord sections after injection of the tracer in the external urethral sphincter. The tracer path was clearly visible in both afferent and efferent neurons from the pudendal nerve, but no interneurons could be detected.

Progress—Wheat germ agglutinin-horseradish peroxidase-labeled neurons have been identified in

[548] The Role of Weightbearing and FES-Induced Exercises on Bone Loss After Acute Spinal Cord Injury

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—Prominent among the metabolic changes after a spinal cord injury (SCI) is the abnormal calcium metabolism that ultimately results in disuse osteoporosis with significant bone loss occurring below the level of injury. The objectives of this study are to: 1) determine if bone resorption can be prevented by exercises which place mechanical stresses across muscle and bone; 2) investigate the reversibility of disuse osteoporosis with vigorous remobilization; and, 3) determine the most effective exercise program in preventing disuse osteoporosis.

Methodology—A group of chronic spinal cord injured patients will be placed on a cycling exercise program powered by functional electrical stimulation (FES-CE). The reversibility of disuse osteoporosis with vigorous remobilization will be investigated in this group. A group of acute spinal cord injured patients will be placed in one of three exercise programs aimed at studying the most effective means to prevent disuse osteoporosis. These exercise programs will include weightbearing through quiet standing, FES-induced isometric exercises, and FES-induced bicycle ergometry. The effects of these exercises on bone loss will be monitored by biochemical methods and by measurements of bone density.

Progress—Progress has been made in determining the effect of muscle contraction versus weightbearing on the reversal of neurogenic osteopenia following SCI. Active recruitment and early data gathering is ongoing in the control group and isometric FES portion of the study.

Results—Of the 10 subjects involved in the chronic SCI study, 8 subjects have completed 9 months of training. All subjects had evidence of significant osteopenia; however, normal parameters of calcium metabolism

reflected the stimulation of bone formation. Measurements of regional bone mass revealed no significant changes. Concomitant endocrine studies revealed a significant increase in parathyroid hormone and vitamin D. These data suggest that although lower extremity FES-CE increases osteoblastic activity, it is followed by secondary hyperparathyroidism which may negate anticipated increments in bone mineral density.

To date, 13 subjects have been enrolled in the acute SCI study of FES-CE. After 12 weeks of training, bone mineral density at the lumbar spine increased slightly, while losses in bone masses were noted at all other sites. There were no significant changes in serum calcium, phosphate, alkaline phosphatase, or osteocalcin with training. However, urine calcium decreased significantly. These preliminary results suggest that FES-CE appears to have no significant effect on preventing osteopenia, but is associated with a dramatic decline in urine calcium excretion.

Future Plans/Implications—Studies will be conducted to determine if secondary hyperparathyroidism observed in chronic subjects is reversible.

Recent Publications Resulting from This Research

Can Functional Electrical Stimulation Cycle Ergometry Reverse Disuse Osteopenia in Chronic Spinal Cord Injury? (Abstract). Bloomfield SA et al., in American Society for Bone and Mineral Research, 1990.

Changes in Regional Bone Mineral Density with Immobilization Due to Spinal Cord Injury (Abstract). Bloomfield SA, Mysiw WJ, Jackson RD, Med Sci Sports Exer 22(2):S76, 1990.

Effect of Functional Electrical Stimulation Calcium and Bone Metabolism in Chronic Spinal Cord Injury (Abstract). Jackson RD, Mysiw WJ, Bloomfield SA, Arch Phys Med Rehabil 71(10):786, 1990.

Hypercalciuria But Not Bone Loss is Prevented by Functional Electrical Stimulation (Abstract). Mysiw WJ, Jackson RD, Bloomfield SA, Arch Phys Med Rehabil 71(10):795, 1990.

[549] Bladder Reinnervation by Anastomosis of L4 VR to L6 VR While Leaving Intact L4 DR as Starter of Micturition

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—The objective of this project is to establish an alternative reflex pathway “skin-CNS-bladder” for micturition. In most spinal cord injured patients, the normal reflex pathway “bladder-CNS-bladder” has been severely damaged. A new pathway would provide a means to bring micturition under voluntary control with the patient initiating voiding by scratching the skin.

Methodology—In rats, the motor nerve of a normal reflex arc above the injury (L4 VR) will be connected to the motor nerve leading to the bladder below the injury (L6 VR), while leaving the intact L4 DR (sensory root) as a starter of micturition. After three months of regeneration, the new pathway will be studied electrophysiologically and by HRP neural tracing. Signals from the skin and muscles remain intact and are used to activate the new micturition reflex pathway.

Progress—The new reflex pathway has been successfully established in terms of histology and is functionally effective.

Results—The results demonstrated that the motor root above the spinal micturition center can be used to reinnervate the bladder, and that the axons can regenerate to at least as far as pelvic ganglia.

Future Plans/Implications—These results have strong potential for clinical application in patients with neuropathic bladders. It may be observed that since impulses from efferent neurons of a somatic reflex arc have been utilized to initiate response of an autonomic effector, it may be possible for similar pathways to be developed for other applications to problems caused by disease or injury to the spinal cord.

[550] Prophylaxis for Deep Vein Thrombosis in Acute Spinal Cord Injury Comparing Two Doses of Low Molecular Weight Heparinoid in Combination with External Pneumatic Compression

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation; National Institute on Disability and Rehabilitation Research*

Purpose—The evaluation of various methods of prophylaxis for deep vein thrombosis (DVT) in acute spinal cord injury remains an important focus of research. Adjusted dose heparin and either low dose heparin or aspirin/dipyridamole in combination with external pneumatic compression have all demonstrated a reduction in the incidence of DVT. A low molecular weight heparinoid (ORG 10172) has been developed which possesses more rapid subcutaneous absorption, a prolonged duration of action, selective inhibition of factors Xa and IIa, and no reported effect on platelets. We conducted a pilot study to evaluate two doses of ORG 10172 in combination with external pneumatic compression (EPC) for the prevention of DVT in the first two weeks following acute spinal injury.

Progress/Methodology—Forty-five patients with C2 through T12 motor complete or motor nonfunctional injury were randomized to receive either ORG 10172, 750 units SC every 12 hours with EPC (Group A), or ORG 10172, 1250 units, SC, every 24 hours with EPC (Group B). The dose of ORG 10172 was blinded to the investigators. All patients underwent daily surveillance with ¹²⁵I fibrinogen scanning and a venous duplex scan on Day 14. Venography was performed on all patients with positive ¹²⁵I fibrinogen or venous duplex scanning. Nineteen patients were randomized into Group A with 16 completing the study. DVT developed in three of the 16 patients (18%). Two of the three DVTS were proximal and the third distal. These developed on Days 6, 8, and 14, respectively. Twenty-six of 30 patients entered into

Group B completed the study. DVT developed in 2 of the 26 (7%). These were isolated calf thrombi developing on Days 7 and 9. The difference between Groups A and B was not significant. The excluded patients in the groups listed above were dropped secondary to medical or physical inability to complete the protocol.

Implications—This analysis indicates that ORG 10172 may be an effective agent for combination prophylaxis in this high risk group of acute spinal cord injured patients and warrants further study.

[551] Spinal Cord Monitoring Using Adaptive Matched Filters

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Sponsor: *Vancouver Foundation, Rick Hansen Man-in-Motion Legacy Fund*

Purpose—During spinal cord surgery, a dedicated system for monitoring spinal evoked potentials is becoming increasingly important for maintaining spinal cord integrity. Thus, the proposed research project is to design and develop a practical spinal cord monitoring instrument which is suitable for use in an operating room environment.

Progress—The proposed approach is that of evoked somatosensory potential measurement. This will utilize dedicated signal processing technology (TMS320) to

provide rapid indication of any changes in the propagation characteristics of the spinal cord.

The signal processing techniques shall consist of a signal-averaging stage, followed by an adaptive matched filter approach containing a generic template. The filter should be able to adapt to the patient's own evoked response, thus able to track any changes that occur, and as well, to eliminate the presurgical time required to obtain the initial template by a nonadaptable matched filter implementation.

[552] Magnetic Resonance Imaging (MRI) Changes Associated with Chronic Post-Traumatic Myelopathy

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Sponsor: *Rocky Mountain Regional Spinal Injury System; National Institute on Disability and Rehabilitation Research*

Purpose—The development of progressive post-traumatic cystic myelopathy is a significant late complication of spinal cord injury and is a common cause of additional late neurologic deterioration. It occurs in from 0.9% to 3.2% of patients with spinal cord injury. Because the predisposing factors and mechanisms which result in cystic extension are poorly understood, a longitudinal prospective study was begun in 1987 to establish the actual incidence, natural history, and MRI correlates of cystic changes in the spinal cord.

Methodology—Specific objectives of the research are to define the incidence and natural history of both the focal form of post-traumatic cystic myelopathy and the progressive form of cystic myelopathy, and identify the MRI correlates of progressive post-traumatic cystic myelopathy

which will identify those individuals at higher risk for this complication.

Progress—Baseline MRIs have been conducted on 100 consecutive cases with the following criteria: traumatic cervical or thoracic spinal cord injury; date of injury between January 1, 1987, and January 1, 1990; Frankel classification A, B, or C upon admission; admitted to Craig within one year of injury; residence at time of injury in Colorado or Wyoming, or regular long-term follow-up planned at Craig; MRI not contraindicated (e.g., substantial internal fixation devices that would interfere with adequate imaging, presence of bullet fragments, pacemakers, etc.). Followup MRIs are being obtained at years 1, 3, and 5.

Preliminary Results—Preliminary analysis of the baseline MRI studies indicate that 32 of 100 cases appear to be completely normal; 50 show minor abnormalities such as cystic degeneration, myelomalacia, or microcystic changes; and 18 demonstrate clear cystic myelopathy. None of the latter showed associated clinical symptoms.

Future Plans—All cases will be followed. At the conclusion of the study, recommendations will be made for further research, programmatic development, and patient follow-up.

[553] Comparative Long-Term Evaluation of Urologic Management Methods

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Sponsor: *Rocky Mountain Spinal Injury System; National Institute on Disability and Rehabilitation Research*

Purpose—The prevailing opinion appears to be that indwelling catheter methods of bladder management are associated with a higher incidence of complications, such as upper urinary tract deterioration, urinary tract stones, pyelonephritis, and bladder cancer. However, the urological clinicians at Craig Hospital have felt that with an active management approach, the risk of complications is lowered considerably. Craig Hospital therefore has begun a prospective longitudinal urinary management study to provide new data that can assist patients and clinicians in determining the relative merits of the variety of bladder management options available.

Methodology—One hundred and eighteen males admitted consecutively after January 1, 1986, were tested to determine their early postinjury bladder and kidney status utilizing various bladder management techniques. They were followed to assess the frequency of urinary complications including clinically significant urinary tract infections for each method. Analysis of differences in outcomes of renal function between individuals utilizing the various methods of bladder management were performed. Specific tests studied included renal plasma flow

values from isotope renographic studies, excretory urogram or intravenous pyelogram studies, number of episodes of chills and fever associated with urinary tract infection, and the presence and location of renal, ureteral, and/or other urinary tract calculi. Data were utilized to compare outcomes in persons using different methods of bladder management. Social and other nonmedical issues relating to bladder management options were also examined.

Progress—Baseline testing is complete on all 118 men, and follow-up studies are scheduled for years 3 and 5 postinjury.

Preliminary Results—Of the 118 cases, 54 are using suprapubic cystostomy, 45 use intermittent catheterization, and 19 are using other methods. Preliminary analysis of baseline testing reveals that 98 of the 118 cases had normal renal function, 9 cases had slight abnormalities, and 11 cases demonstrated abnormal renal function (including 2 cases with associated trauma to the kidneys, 1 with pre-existing renal disease, 1 with acute renal disease, and 3 with significant medication interactions). All will be followed for 5 years.

[554] Comparative Effectiveness of Two Methods of Weaning Quadriplegics From a Ventilator

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Purpose—This study has been designed and implemented to compare the relative effectiveness of weaning persons with quadriplegia from the ventilator. The two current

methods used for weaning include: 1) Synchronized Intermittent Mandatory Ventilation (SIMV); and, 2) Progressive Ventilator Free Breathing (PVFB). Because

Craig Hospital has had clinical success with PVFB, while many other hospitals attempt to wean persons with quadriplegia from the ventilator using SIMV, a prospective study comparing these two methods is being conducted.

Methodology—A randomized control group who meet the study selection criteria and agree to participate in the study will be randomly assigned to one of the two weaning protocols. Criteria includes patients who are less than 65 years old and have injuries below the C-3 level and are otherwise medically stable; absence of significant head injury; no major respiratory problems such as active asthma, pneumonia, atelectasis above stage one, or acute respiratory disease; existence of at least one volitional diaphragm and a vital capacity of greater than 50 cc; and physician's agreement that the patient is ready to wean and patient's willingness to participate. Random assign-

ment to the two conditions will be made within three strata of initial vital capacities (under 500 cc, 500-1000 cc, and over 1000 cc), which are assumed to have different likelihoods of successful weaning.

Progress—All protocols have been designed and the study is currently underway.

Implications—In patients with quadriplegia who are ventilator-dependent, it has been observed that a certain number, in whom SIMV is utilized, will progress to a certain point and then stall in the weaning at that point. By comparatively testing the effectiveness of these two approaches, criteria can be established as to whether one method is safer, faster, and/or more successful than the other ventilator weaning method, and whether or not one method results in fewer complications and fewer indications of stress than the other.

C. Spinal Cord Regeneration

[555] Toward Better Methods of Nerve Repair and Evaluation

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Sponsor: VA Rehabilitation Research and Development Service (Project #B003-4RA)

Purpose—The goal of this research is to provide a means for repair of nerve function. This includes cases of nerve injury within intact limbs, connection of nerves in an amputation stump to a prosthetic limb, and functional neuromuscular stimulation (FNS) applications in spinal cord injury. It is felt that all of these modes of nerve repair can be achieved using a general-purpose neural interface, capable of recording from and stimulating small groups of axons that have regenerated through holes in the device.

Methodology—To verify the basic design concepts, passive neural interfaces were implanted in the peroneal nerves of 12 Sprague-Dawley rats to be evaluated 1-year postoperatively. To optimize the designs in terms of nerve regeneration, a second study using 30 rats is underway. A new surgical coupler design is being used to implant several different "via hole" designs, geometries, and densities (varying the total percentage of nerve cross-sectional area available for regeneration). The results will

be evaluated using extraneural stimulation and compound action potential recording to assess the degree of nerve regeneration for each implant (controls are fully occluded and fully open silicon devices). In addition, work is progressing on technology development for active versions of the neural interfaces, including amplifiers and related circuitry.

Progress—There has been considerable progress in functional demonstration and refinement of the neural interface technology. Early devices with laser-drilled holes through the silicon were made using fabrication technology that was not compatible with inclusion of the microelectronic devices required for future versions. Active circuit compatible fabrication processes were developed that led to the realization of passive microelectrode arrays with thin-film iridium microelectrodes, silicon nitride passivation (insulation) layers, and plasma-etched via holes. The basic stimulation and recording properties of these passive neural interfaces

have been examined *in vivo*. This information is being used to refine the designs of the devices. Progress has also been made in the area of development of interconnect technology (to allow the neural interfaces to be wired to external electronics), improvement of the fabrication technology, and the implementation of active circuits to be included with the neural interfaces.

Results—Electrophysiological tests on the first group of passive neural interface implants demonstrated regeneration of the axons through the holes and the ability to both stimulate with and record from the neural interfaces. Test devices for the second study have been successfully fabricated and are being implanted, with results expected in 1991. New surgical couplers (to overcome limitations of those used for the early work with laser-drilled devices), preliminary Teflon-coated wire interconnects to the neural interfaces, fabrication improvements, and computer simulations of the new active microcircuits have yielded encouraging results.

Future Plans—In order to successfully realize directly interfaced limb prostheses as our first clinical milestone, we must implement an advanced version of the neural interface with on-chip amplifiers for recording, current sources for stimulation, and associated circuitry. A prototype of this device for *in vitro* experiments, which has already been designed and tested, will be modified to

meet these requirements. These modifications would entail the inclusion of new active microcircuits, through-chip via holes and the passivation coating required to protect the microcircuits from body fluids. This work is currently underway.

Recent Publications Resulting from This Research

Fabrication Techniques for Directly Implantable Microelectronic Neural Interfaces. Kovacs GTA et al., in Proceedings of the 12th Annual RESNA Conference, New Orleans, LA, 292-293, 1989.

Accurate Small-Signal Characterization of Microelectrodes. Kovacs GTA et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 381-382, 1990.

Development of a Neural Network Interface for Direct Central Nervous Control of a Prosthetic Limb. Wan EA et al., in Proceedings of the International Joint Conference on Neural Networks, Washington, DC, 1990.

Technology Development for a Chronic Neural Interface. Kovacs GTA, PhD diss., Technical Report No. E073-1, Stanford University, 1990.

A Method for Evaluating the Selectivity of Electrodes Implanted for Nerve Stimulation. Liang DH et al., in Proceedings of the IEEE Engineering in Medicine and Biology Society (in press).

Nerve Repair at the Axon Level: Long Term Regeneration of Axons in Rats and Primates Through Laser-Drilled Holes in Silicon Chips. Rosen JM, Grosser M, Hentz VR, J Reconstr Neurol (in press).

Awards

The Peter J. Gingrass Memorial Award of the Plastic Surgery Research Council was given to Gregory Kovacs for his presentation of this research.

[556] Axonal Regeneration in Artificial Nerve Graft Model

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Sponsor: VA Rehabilitation Research and Development Service (Project #B387-2RA)

Purpose—Indications for nerve grafting vary from gaps of 1 cm to greater than 5 cm or more before a graft would replace an end-to-end repair under tension. Where a graft is indicated, autografts are the preferred method at the present time. The autograft fulfills three major requirements for an ideal nerve graft: 1) it acts as a *passive* conduit for axonal regeneration; 2) it is a *natural* substitute which is immunologically acceptable; and, 3) it is vascularized by the recipient bed as a free graft. The major limitation of the autografts is the requirement of a donor nerve. Homografts and heterografts have been evaluated as an alternative to autografts, but have been found to be immunologically unacceptable. Therefore,

the development of an artificial nerve graft is necessary to solve both problems of availability and rejection by the immune system.

The purpose of this study is to examine the regeneration of the peripheral nervous system through an artificial nerve graft composed of a synthetic conduit of collagen and fibrin filled with a collagen type I matrix.

Methodology—Five monkeys had experimental gaps of 30 mm created in six nerves in each animal (two each of dorsal branch of ulnar, dorsal branch of radial, and the palmar cutaneous branch of the median nerve). These gaps were repaired with one of three possible methods:

1) sutured autograft; 2) collagen/fibrin tube filled with collagen type I; or, 3) collagen/fibrin tube filled with heparinized saline. Ten repairs of each method were performed. Nerve repairs will be evaluated at 9 months by histological, physiological, and end organ evaluations (sensory).

Progress—The long-term study has been set up in five primates. These animals will be evaluated after 9 months.

[557] Artificial Nerve Graft: Union of Cellular and Noncellular Components

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Purpose—Injuries to peripheral nerves may result in a significant loss of tissue which requires a graft to bridge the gap between the transected ends. Presently these gaps are reconstructed using autografts. However, the autograft causes morbidity at the donor site, and in cases of major nerve loss there may not be sufficient donor nerve available to span the clinical nerve gap. In this study, an artificial nerve graft composed of viable cultured Schwann cells, oriented collagen type I, and a synthetic conduit will be employed to study regeneration across a 10 mm gap in the rat peroneal nerve.

Methodology—The protocol is divided into four phases during the proposed 3-year study. The first phase concerns itself with the isolation and purification of Schwann cells in culture. The second phase involves the preparation of the graft. This phase consists of the orientation of collagen type I fibers with added cultured Schwann cells and insertion into a glycolide trimethylene carbonate (GTMC) conduit. Phase III moves to the *in vivo* aspect of the study where the artificial nerve graft will be compared to autografts, collagen-filled GTMC tubes, and empty GTMC tubes in the regeneration of peripheral nerves. The final phase covers the evaluation of the nerve repairs with the various grafts. Short-term (3 months) animals will be evaluated by qualitative histology only, while long-term (12 months) animals will be evaluated

Implications—The results of this study should provide us with direction toward a larger mixed nerve primate study before proceeding to clinical trials.

Recent Publications Resulting from This Research

Artificial Nerve Graft Compared to Autograft in a Rat Model.

Rosen J et al., J Rehabil Res Dev 26(1):1-14, 1989.

Artificial Nerve Graft Using Collagen as an Extracellular Matrix for Nerve Repair Compared to Sutured Autograft in a Rat Model. Rosen J et al., Ann Plast Surg (in press).

noninvasively every 2 months via toe-spread analysis (functional test) during the regenerative period, and with qualitative histology, transmission electron microscopy, fiber diameter histograms (quantitative histology), electrophysiology, and twitch-tension analysis (functional test) at the end of the regenerative period.

Progress—The study is currently at Phase III, with the use of the collagen type I/Schwann cell/GTMC grafts for the repairs of 10 mm gaps in the rat peroneal nerve. Controls have been set up using matched pairs and consist of empty GTMC tubes, sutured autografts, and collagen-filled GTMC tubes. Within 2 months, an evaluation (Phase IV) of the short-term animals will begin.

Results—We have demonstrated that the Schwann cells survive in the graft *in vitro*. We have also now begun to isolate glial growth factor, a potent mitogen for Schwann cell growth *in vitro*.

Future Plans—The combination of cellular and non-cellular components should provide an ideal environment for regeneration. Our initial studies in the rat model should lead to follow-up studies with longer gaps in a primate model. The long-term goal of this project is to improve the clinical results of peripheral nerve graft reconstructions.

[558] Regeneration and Functional Recovery in Neural Tissue

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Purpose—The overall goals of this project are to increase the fundamental knowledge of factors that govern peripheral nervous system (PNS) and central nervous system (CNS) nerve fiber growth and maintenance, as well as survival of the parent neuronal cell body, and to better understand mechanisms involved in the development of connections and adaptation and behavioral plasticity in different areas of the CNS.

The individual projects will investigate: 1) non-neuronal cell secretory products (both soluble and insoluble) that promote CNS neurite growth and neuronal survival in the animal and in culture; 2) regenerative potential of cultured CNS growth cones under differing environmental conditions to better understand differences in growth capacity; 3) distribution and molecular associations of myosin, actin, and several actin-associated proteins in cultured growth cones, to clarify mechanisms responsible for oriented growth of neuronal processes;

4) improving functional recovery following nerve repair by ameliorating the response of sensory neurons to injury with the administration of nerve growth factor; 5) the role of synaptic transmitters in visual cortex development; 6) physiological and morphological substrata for the process of adaptation of the vestibulo-ocular reflex; 7) response properties and connections of surviving somatic sensory cortex that receive cortical lesions in infants versus adults, to search for the basis of observed behavioral recovery in the infant; and, 8) cerebellar unit and spindle afferent firing, reflex electromyographic changes, and stiffness and damping of the monkey's wrist during prevention of oscillations produced by novel loads through adaptive (plastic) control of movement behavior.

Implications—The results will facilitate progress toward better understanding basic mechanisms of regeneration and useful plasticity.

[559] Recovery and Regeneration After Spinal Neuron Injury

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Purpose—This program is a continuing investigation of the effects of injury to spinal nerves or to spinal cord tracts upon the functional organization of vertebrate spinal neurons. The overall goal of this program is to provide data on the degree to which functionally effective regeneration or reorganization of spinal neurons and their connections can take place in immature or mature vertebrate nervous systems. Each of the projects has its counterpart or point of departure in deficits suffered by human beings after disease or traumatic injury of the spinal cord and/or of the nervous processes of spinal neurons.

Methodology—The approaches are interdisciplinary and employ animal models, in which combinations of physiological, morphological, biochemical, and behavioral measures are combined in various ways to test for exam-

ples of: 1) regeneration or reorganization of spinal pathways in vertebrates; 2) changes in the organization of spinal reflexes involving the kidney and bladder after spinal cord injury; 3) conditions favoring functionally effective reinnervation of the urinary bladder by foreign nerves; 4) factors associated with the specificity of reinnervation and regeneration after injury of sympathetic preganglionic neurons; 5) changes in utilization of amino acids and associated modification in cytoskeletal protein synthesis by motoneuron cell bodies after injury of their axons; 6) modifications of the projections into the spinal cord of thin afferent fibers after injury of dorsal roots and associated alterations in functional properties of neurons in laminae I and II; and, 7) modifications in the distribution of chemical markers for primary afferent fibers, such as peptides in the spinal gray matter, after injury of ascending spinal pathways.

[560] Center for Acute Spinal Cord Injury

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Purpose—Injury to the spinal cord initiates a complex cascade of events, the net effect of which is a behaviorally limiting neurological deficit. Innumerable investigations of spinal cord injury have led to the realization that in order to improve the neurological outcome of patients, we must first understand the basic mechanisms that promote differentiation and growth in the developing nervous system and regeneration and repair in the adult. This program is designed as a coordinated effort to identify basic cellular mechanisms influencing degeneration and regeneration in the central nervous system (CNS) following injury. The goal of the program is to develop a body of knowledge sufficient for identifying and understanding basic mechanisms which may be susceptible to intervention strategies leading to an improvement in neurological outcome.

The program is divided into six major areas: 1) a core facility providing for electron microscopy studies; 2) a core facility providing for administrative support;

3) studies focused on trophic factors and membrane components that may influence regeneration; 4) analyses of mechanisms influencing sprouting and reactive synaptogenesis; 5) characterization of functional capacities of regenerating neurons, including the activity of voltage-dependent channels; and, 6) cytochemical and genetic mechanisms underlying regeneration and the role of the genome in reactivating specific developmental genes potentially important in regenerative responses.

Implications—These studies will fill critical gaps in our current understanding of regenerative responses in the developing and adult CNS. This knowledge is crucial for the development of successful strategies for treating spinal cord injury, injuries elsewhere in the CNS, and disease processes involving the progressive loss of populations of neurons, such as that which occurs in Alzheimer's dementia.

[561] Spinal Cord Injury Research Center

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Purpose—Spinal cord injury and its eventual outcome is a product of the cellular and molecular mechanisms of degeneration, growth, and regeneration. These processes may be understood best by a combination of studies which examine the acute and chronic mechanisms of degenerative phenomena. In addition, since the capacity to regenerate spinal neurons is limited in the adult spinal cord, an attempt to examine regenerative phenomena during development, when such phenomena are enhanced, is an important part of this research.

Methodology—The specific aspects of these phenomena to be explored include an examination of the biochemical pathophysiology of degeneration, and the physiology, biochemistry, and anatomical characterization of reorganization of nervous tissue subsequent to nerve trauma. The further development and evaluation of a new injury device is an important step toward the control of injury

as an independent variable. Alterations in lipids, membrane integrity and recovery, and the ability to induce changes in the metabolic (PO_2) or ionic (Ca^{++}) microenvironment will be studied to assess the effects of ischemia or impact injury to the spinal cord. Interventions into this pathological process will also be attempted with naloxone to improve tissue oxygenation and spinal hypocalcemia. The degree to which such interventions are successful will also be assessed chronically by behavioral or morphometric analysis.

Mechanisms of axolemmal synthesis will be studied by assessing ganglioside contributions to peripheral nerve trauma. Reorganization and regenerative phenomena will be assessed in the cat and developing frog, respectively, using horseradish peroxidase (HRP) histochemistry, intracellular neurophysiological techniques, and electron microscopy. The role of nerves in the regenerative plasticity involved in limb regeneration will also be assessed.

Implications—Only by studying acute alterations in spinal pathophysiology and attempting to reverse them chronically can we begin to effect changes in the capacity

of the central nervous system to use the inherent mechanisms of regeneration that it initially had, but may have lost during development.

[562] Mechanisms of Recovery After Spinal Cord Injury

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Purpose—We propose to investigate the mechanisms accounting for, limiting, and encouraging the recovery of function after spinal cord damage. Recovery from the level of the neuron to that of the whole animal's behavior will be examined. We wish to determine which aspects of neuronal plasticity, including sprouting and regeneration, may contribute to recovery. A clearer understanding of the nature, extent, and regulation of neuronal plasticity should lead to rational strategies for enhancing the extent and quality of recovery from spinal cord injury. Our long-range goal is to find methods that can enhance recovery mechanisms, and determine if those methods improve functional recovery after damage to the spinal cord.

Methodology—Our experimental models are the cat and rat spinal cords. Our experimental approach is multidisciplinary, including intra- and extra-cellular recording from axotomized and deafferented neurons; regulation of synthesis of mRNA coding for proteins in axotomized neurons; the use of neural transplants to enhance regenerative potential; morphological examination of regeneration and sprouting in spinal neurons; and behavioral examination of recovery of motor function following spinal cord damage. Correlative studies include electron

microscopic and physiological studies of reinnervation of partially denervated neurons; metabolic and morphological studies of recovery of damaged neurons; morphological, biochemical, and physiological studies of the determinants of regeneration; and morphological and behavioral studies of recovery of function.

In projects 1 and 2, investigations of physiological and morphological correlates of axotomy and regeneration of spinal and brain stem motoneurons are proposed; the differences in gene expression between regenerating and nonregenerating neurons will be explored in project 3; the increased potential for CNS regeneration elicited by embryonic transplants will be examined in project 4, including an investigation of synapse formation by the regenerating axons. In project 5, light microscopic-electron microscopic correlates of sprouting of spinal systems will be examined quantitatively to learn the rules that determine successful reinnervation; project 6 uses Clarke's nucleus as a model for studying morphological and physiological correlates of recovery of deafferented or axotomized neurons (including physiological consequences of reinnervation and metabolic determinants of survival of damaged cells); and, in project 7, behavioral and anatomical correlates of recovery of function and lesion-induced sprouting will be explored.

[563] Recovery of Function After Spinal Cord Injury

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Purpose—A number of studies have shown that embryonic transplants can ameliorate some deficits or mediate recovery of function following central nervous system (CNS) damage. Often these effects are due to diffuse release of hormones or transmitters and are independent of the formation of specific connections that replace the

damaged pathways. We intend to test the hypothesis that after spinal cord damage at birth, embryonic spinal cord transplants mediate recovery/sparing of specific motor functions by permitting the anatomical elongation of specific damaged supraspinal pathways into spinal motor centers.

We have shown that after spinal cord injury at birth, spinal cord transplants prevent the retrograde cell death of immature axotomized neurons and support the growth of certain populations of axons across the site of a neonatal spinal cord transection. Recent preliminary work in this laboratory indicates that such transplants enhance the development and recovery of motor function. The aim of the current project is to determine the extent to which, and the mechanisms by which, the transplants mediate recovery of function following spinal cord injury.

Methodology—We will examine four representative pathways which are at different stages of development at the time the lesion is made: corticospinal, raphe-spinal, coeruleo-spinal, and dorsal root afferents. We will use neuroanatomical and neuropharmacological techniques to assess the influence of these pathways on recovery of function following spinal cord damage at birth, and we will examine how the response of the immature spinal

cord changes during development to produce the more restricted response to injury which is characteristic of that observed in the mature spinal cord.

Motor function will be measured by qualitative and quantitative assessment of the animal's ability to perform a battery of reflex and locomotor tests which are designed to evaluate specific components of the animal's sensorimotor capacity.

Results/Implications—If the pathways that grow through the transplant are individually ablated and specific functions are disrupted, that would support the hypothesis that the anatomical reorganization of these specific pathways mediate the recovery of motor function.

We hope to gain a better understanding of the mechanisms of recovery of function and anatomical reorganization in this animal model of spinal cord injury, in the hope that improved therapeutic approaches in human spinal cord injury can be identified.

[564] Spinal Cord Injury and Repair

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Purpose—This program on spinal cord injury represents a blending of interdisciplinary approaches to explore the potential for restoring function in the injured spinal cord. With this long-term objective in mind, various anatomical, behavioral, electrophysiological, neurophysiological, and microsurgical methods will be used to achieve the following immediate goals: 1) to examine the capacity of fetal central nervous system (CNS) and peripheral nervous system (PNS) grafts to mediate anatomical and functional repair in acute and chronic injuries; 2) to develop models that will ultimately permit definitive correlative analyses of therapeutic strategies aimed at restoring sensory, motor, and/or autonomic function; 3) to test new approaches that may permit in-depth studies of behavior and cellular neurophysiology; and, 4) to demonstrate fundamental events underlying functional recovery in the amphibian spinal cord.

Methodology—The program is divided into eight project areas. Project 1 will examine the ability of fetal CNS grafts to establish host-graft synaptic interactions in the chronically injured spinal cord, as well as the capacity of

these grafts to prevent the death of certain spinal neurons following cord damage in the adult rodent; methods will also be developed for intraspinal transplantation into the adult cat in conjunction with our Core laboratory.

Project 2 will utilize electrophysiological methods to document changes in segmental and descending such post-injury alterations.

Project 3 focuses on the problem of spasticity, as manifested in the cat, and seeks to establish approaches that will permit direct correlations between non-invasive physiological evaluations and electrophysiological recordings.

Project 4 will test the efficacy of PNS grafts in restoring somatosensation and segmental reflex activity in the cat and primate.

Project 5 will study the neurophysiology and synaptic organization of the cat sacrocaudal cord—a region which may serve as a novel model for studies of spinal cord plasticity and regeneration.

Project 6 will explore sensory physiology and the ascending pathways that subserve cortical perception of respiration in various animal models, as well as in humans with spinal cord injuries.

Project 7 addresses the afferent component of the penile reflex pathways in the rat.

Project 8 will examine some of the variables that influence plasticity, regeneration, and functional repair in the amphibian spinal cord.

Implications—Collectively, these subprojects will provide a comprehensive and interactive investigation of various aspects of spinal cord motor, sensory, and autonomic function that are of fundamental scientific and clinical interest.

[565] Novel Cell Lines for Spinal Cord Transplantation

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Purpose—To optimize central nervous system (CNS) graft survival, fetal donor tissue is essential. Given the ethical and logistical constraints of obtaining human fetal tissue to replace damaged CNS tissue, one alternative strategy is the development of CNS cell lines whose mitotic activity and differentiation *in vivo* can be regulated. The goal of this research is to develop such cell lines, characterize their differentiation *in vitro*, and begin to address their potential as replacement for damaged CNS neurons and oligodendrocytes.

Methodology—Immortal, temperature-sensitive (ts) cell lines will be developed by infecting neuroepithelial precursor cells with a retrovirus encoding the ts-mutant of the SV40 large T transforming protein. The rationale for this strategy is that cells transformed with this construct are mitotically active at permissive temperatures (33 degrees C). At 39 degrees C the thermolabile oncogenic protein is inactive, the cells stop dividing and resume differentiation, presumably in the direction that was interrupted at the time of viral infection. The ts-cell lines will be developed from E13 medullary raphe nucleus

(RN), in an attempt to generate oligodendrocytic, serotonergic and GABAergic tsRN cell lines.

Isolated tsRN cell lines will be grown under differentiating conditions and characterized for the expression of astrocytic-, oligodendrocytic-, and neuronal-specific antigens. Oligodendrocytic-differentiating tsRN cell lines (oligo-tsRN) will be screened for the ability to myelinate dorsal root ganglion neurons *in vitro*. Myelinating oligo-tsRN cell lines will be transplanted into the spinal cord of the myelin-deficient rat and myelin formation *in vivo* assessed.

Neuronal tsRN cell lines will be further analyzed for the ability to synthesize and release 5-HT and GABA. Positive cells will be transplanted into a 5,7-DHT lesioned spinal cord and biochemically and immunohistochemically assessed for the ability to replace denervated 5-HT fibers. If GABAergic tsRN cells are not obtained, one neuronal, nonserotonergic tsRN cell line will be transfected with the glutamic acid decarboxylase (GAD) cDNA and a GABA-tsRN cell line isolated. The tsRN TGAD cell line will then be transplanted into adult ventral spinal cord and assayed for the ability to secrete GABA *in vivo*.

[566] Repair of Injured Nervous Tissue with Foreign Grafts

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Purpose—A short gap in a peripheral nerve can be repaired with a living nerve graft, dead tissue that contains basement membrane tubes (e.g., a frozen nerve graft), or an artificial tube (e.g., a silicone tube) that is initially filled with a fibrin gel. We are analyzing these methods of repair in rats using electron microscopical

and histochemical techniques to ascertain how regeneration occurs in each, and whether aspects of nerve function are restored. The perineurial-nerve barrier (PNB) and the blood-nerve barrier (BNB) regulate the movement of macromolecules into the endoneurium from around the nerve and from endoneurial blood vessels respectively.

In previous studies, the PNB and BNB were restored in living nerve grafts, whereas in nerve segments formed in silicone tubes, the PNB developed, but the BNB did not.

Methodology/Results—To better understand barrier formation, we performed a developmental study using the barrier tracer horseradish (HRP). The results indicated that the nerve barriers matured at different times. The PNB kept HRP out of the endoneurium for 2 weeks, but for a time it leaked out of the BNB (i.e., from endoneurial blood vessels). The BNB did not retain intravenously-injected HRP until 6 to 8 weeks postnatally. In contrast to the blood-brain barrier (in which certain enzymes appear), the endothelial cells of the endoneurial blood vessels did not develop any gamma glutamyl transpeptidase

activity, and alkaline phosphatase appeared long before the BNB became intact. In an analysis of cellular events occurring in silicone tubes, we found that the cable within it could form in the absence of axons present in the proximal nerve stump. Indeed, this type of cable could support axonal growth through it later on, after a normal nerve end was joined to it. Because the nerve segment formed in a tube is not morphologically normal, we injured it to determine whether this cable would undergo Wallerian degeneration and support axonal regeneration again. As expected, a crush injury of an axonal-containing cable formed at 4 months paralyzed the leg of the rat. After 8 weeks, the leg recovered movement and the nerve cable contained regenerated axons in various stages of remyelination.

[567] Muscle Function Recovery After Peripheral Nerve Injury Enhanced by Chronic Direct Current Stimulation

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Sponsor: Research Communities of Slovenia, Ljubljana, Yugoslavia

Purpose—Using an animal model, we will determine the optimal direct current stimulation parameters for enhancing nerve regeneration and muscle function recovery after nerve crush injury. Understanding the mechanisms involved in weak chronic DC stimulation will enable further study which could benefit patients with peripheral nerve and spinal cord injury.

Progress—We have developed and tested a simple *in vivo* quantitative method for measuring changes in muscle function during denervation and reinnervation of plantar flexor muscle of rats. An implantable DC stimulator with wick electrodes was also designed. We studied muscle function recovery after nerve crush under the influence of DC currents. The animals were randomly divided into three groups: CA (cathode distally to the site of axotomy); AN (anode distally); and, SH (with sham implants, identical in size, shape, and weight to the real one, battery replaced by a piece of noncorrosive metal). Isometric contraction of plantar flexors was recorded during reinnervation, as a measure of muscle function

state. The force of tetanic contraction was assessed in a period of six consecutive weeks, once weekly.

Results—Muscle force returned to the control value during the fourth week in cathode-stimulated rats, and in the fifth week in anode and sham group. The differences are statistically significant (two-tailed, unpaired Student *t*-test).

To facilitate our understanding about how the cell translates the electrical signal into a functional answer, as well as future studies of the complex changes during *in vivo* nerve regeneration and possible beneficial effects of DC, we united the relevant current knowledge with our assumptions into a simplified qualitative model of peripheral nerve regeneration after crush lesion.

Recent Publications Resulting from This Research

Nerve Regeneration and Externally Applied Electric Field. Ribaric S, Stefanovska A, Bresjanac M, in *Advances in External Control of Human Extremities*, D.B. Popovic (Ed.), Nauka, Yugoslavia, 497-507, 1990.

XVI. Wheelchairs and Powered Vehicles

For additional information on topics related to this category see the following Progress Report: [118].

A. General

[568] Adaptation of Wheelchair Standards for VA Policy and Purchasing Requirements

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Sponsor: VA Rehabilitation Research and Development Service (Project #B228-2RA)

Purpose—The purpose of this project is to complete the development of standards for wheelchairs; design a pilot database for collection and use of wheelchair standards testing data; and develop guidelines for use of the standards by clinicians.

Progress—All 17 parts of the standards have been completed and have been submitted to the American National Standards Institute (ANSI) for approval. Standards submitted to ANSI generally are approved within 3 to 6 months of submission; it is expected that ANSI-approved standards will be available no later than March 1991.

The pilot database has been completed and is ready for beta testing. It was developed by RehabTech Associates of Ellicott City, MD in accordance with the Department of Veterans Affairs (DVA) and the Association for the Advancement of Rehabilitation Technology (RESNA) specifications.

The clinical guidelines are in the process of final revision and will be submitted to DVA for review.

Methodology—The wheelchair standards have been developed over a 10-year period by a committee of rehabilitation engineers, clinicians, wheelchair manufacturers, distributors, wheelchair users, and federal agency (DVA and FDA) representatives. The United States (US) committee has coordinated its standards development efforts with those of the International Standards Organization (ISO) so that wheelchairs produced the world over are held essentially to the

same standards. This will make it easier for US users and dealers to import wheelchairs for their use and for US wheelchair manufacturers to export wheelchairs for sale in other countries.

The database was developed in response to needs and requests outlined by the DVA and the Wheelchair Standards Committee. It includes test data disclosure formats for individual wheelchairs, as well as the capability of comparing the performance of two or more wheelchairs on any given test, and the capability of compiling data for all wheelchairs tested.

The clinical guidelines were developed based upon the recommendations and suggestions of DVA clinicians. The guidelines also utilize additional input from the US and ISO committees.

Results—Once the standards have received final ANSI approval, they will be reviewed on a yearly basis by the US committee, and changes/modifications may be made to these standards based upon that review. Copies of the standards are available through RESNA (the official standards development organization of record) and through ANSI.

Information about the availability of the database program, comparative data, and clinical guidelines also can be obtained from RESNA.

Recent Publications Resulting from This Research

Wheelchair Standards: Pushing for a New Era. Axelson P, Phillips L, Homecare, October, 1989.

[569] Comparative Study of 19 Wheelchairs

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Sponsor: *American Association of Retired Persons*

Purpose—Eleven participants with an average age of 67 tested 19 different wheelchairs provided by manufacturers.

Methodology—Users were asked to open and fold, get into and out of, operate all components (wheel locks, footrests, etc.), and lift each wheelchair. Each subject was timed and asked his/her opinion about the “ease” of completing each task, as well as their “sense of stability” when entering and exiting the chair.

Later, each appliance was put through its paces on an obstacle course. Participants maneuvered these chairs on a 25-foot hard wooden floor, carpeting, a gravel surface, and a 20-foot ramp. Every task was timed, the number of strokes counted, and participants queried about the performance of each chair. The distance covered with one stroke of the wheel was also measured.

Results—Our subjects found the standard chair compared favorably with lightweight and ultralight chairs on hard flooring, but not on carpeted or gravel surfaces. Standard chairs took less time to open/fold, but the additional weight of these chairs slows them down. Standard chairs consistently took more time to complete their trials and didn’t travel as far with one stroke.

Lightweight chairs performed better in rollability than standard chairs, but came in second to ultralights. They took longer to open and fold than the other chairs.

Ultralights performed best of all in climbing a ramp, similar to a “curb cut,” or that portion of sidewalks cut away for wheelchairs at street crossings. The reasons for this could be twofold. First, compared to a standard chair, the lightweight goes further with a single stroke.

Second, for the inexperienced, an ultralight chair tends to buck or raise up when the wheel is pushed hard, such as going up a slope. Antitipping devices prevent it from going over, but using an ultralight requires practice. Although our testers practiced with each chair before each trial, none of them had used anything but standard chairs before this test.

Ultralight chairs, which often have fewer structural components, appear to provide less support, but our evaluators felt they were no less stable than standard chairs. Sixty-five percent of the participants could lift an ultralight chair 16 inches, when only 25 percent could lift their own (standard) chairs.

Ultralights performed best in crossing carpeted and gravel surfaces and rolled further than the other two chairs on all three surfaces (hard flooring, carpeting, and gravel surface). Participants had difficulty manipulating the front rigging, but found the wheel locks on the inflatable tires easier to apply than on the other chairs.

Many users have never been properly fitted. The personal chair of every evaluator was reviewed before testing began, and only one out of the 11 was fitted according to standard sizing guidelines. The chairs were too wide, too high, or too low. In one instance, the variance was more than five inches. At best, an ill-fitting chair is uncomfortable. At worst, it causes bruises, poor posture, pressure sores, and limits mobility.

Recent Publications Resulting from This Research

AARP Product Report on Manual Wheelchairs. Norrgard L, Cremaldi E, Wylde M. Washington, DC: American Association of Retired Persons (in press).

[570] Costs and Benefits Associated with Limiting Deep Discharge of Wheelchair Batteries

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Sponsor: *Channel 7 Children’s Medical Research Foundation of S. Australia*

Purpose—The effect of avoiding all excursion by wheelchair batteries into deep discharge on the life of the

batteries is being investigated with a view to reducing the cost of this major item in electric wheelchair operation.

The cost of enforcing this avoidance of deep discharge is also being evaluated, considering user convenience, technology required, and safety.

The objective is to maximize battery life and minimize inconvenience and complexity of control of electric wheelchairs.

Methodology—Three groups of wheelchair users were identified: 1) “bad” users who constantly fail to achieve 6-months’ life from battery sets; 2) “normal” users with a variety of electric wheelchairs; and, 3) “normal” users who have low-voltage cutoff devices fitted to their wheelchairs. Fifty percent of Group 1 had low-voltage cutoff controls fitted, 50% remain unaltered.

All groups were fitted with new batteries and capacity checks and replacement records were kept. Any significant changes in the users’ lifestyles were also noted (e.g., sporting interests, change from school to employment).

Progress—Testing is continuing, since many of the subjects are still on their original set of batteries. However, indications are that it is cost-effective to limit the degree of discharge. After the familiarization period, no complaints have been received concerning the reduced distance covered per battery charge, and all participants are successfully avoiding the deep discharge cutoff point during their daily use of wheelchairs.

[571] International Wheelchair Standards: A Study of Costs and Benefits

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Sponsor: Channel 7 Children’s Medical Research Foundation of S. Australia

Purpose—The purpose of this study was to compare the total purchase and ownership costs of electric wheelchairs meeting International Standards requirements, with apparently cheaper wheelchairs that do not meet these standards.

Methodology—Models of wheelchairs that complied with requirements based on ISO 7176 were identified and samples were subjected to laboratory tests simulating one year’s active use. Accurate account was kept of failures, repair costs (labor and parts), and downtime.

Wheelchairs that did not comply with the requirements based on ISO 7176 were then subjected to identical testing and the two sets of costs compared.

Results—The initial group sizes were as follows: 1) 10 participants; 2) 20 participants; and, 3) 20 participants.

Group 1 had an increase of 34% in battery life when fitted with voltage limiting controllers; Group 1 with existing controllers had an increase of 8% in battery life; Group 2 had a 2.4% increase in battery life; and, Group 3 had a 9% increase in battery life.

Implications—The inferences that can be drawn at this stage are that there is a general increase in usable life of battery sets due to improved regulation of chargers and the availability of larger ampere hour capacity batteries more suited to the daily demands of our young clientele. The second inference is, from the results of Group 1, that the provision of low-voltage cutoff facilities in a wheelchair controller contributes significantly to the life of a battery set. The researchers feel it is too early to come to clear conclusions, as many of the users are still on their first battery set, and the effect of a winter season on wheelchair batteries has yet to be accounted for.

Future Plans—The testing will continue until all users have exhausted at least one battery set, and a full year’s cycle has been completed. The advent of microprocessor-controlled wheelchair controllers, with a programmable low-voltage cutoff facility, will enable us to investigate the effect of different levels of voltage cutoff on battery life, and thus, operating costs.

Progress—Eight parts of ISO 7176 have now been published, also six parts of the Australian Standard AS 3696, which set out testing methods and procedures. Publication date for the full Australian Standard, *Wheelchairs, Product Requirements*, is scheduled for this year.

Testing of two brands of standards quality and non-standards quality powered wheelchairs has been completed.

Calculations have been made of running costs, repair costs, and costs of upgrading current production wheelchairs to standards quality. These calculations included allowance for design time, testing costs, updating of drawings and manuals, and disposal of obsolete parts. They did not include costs of reduced warranty claims or

indirect expenses incurred by wheelchair breakdowns (e.g., alternative transportation and rescue operations). The upgrading process is within the capacity of most manufacturers.

Results/Implications—The study indicated most clearly that standards-quality electric wheelchairs are good economic propositions, the extra initial cost being recouped well within the first year of use.

Benefits of using a standards-quality wheelchair in our tests included an increase in mean distance between failures (MDBF) from 261 to 6,000 kilometers, a 68%

decrease in the total number of faults (ISO Class 1, 2, and 3), and a reduction of 92% in repair time for the standards-quality wheelchairs.

The testing laboratory has now received full National Association of Testing Authorities accreditation for wheelchair and rehabilitation equipment mechanical testing.

Recent Publications Resulting from This Research

Wheelchairs Headed Where? An Overview. Hartridge M, Garrett RE, Seeger BR, in Proceedings of TADSEM '89, 47-50, 1989.
International Wheelchair Standards: A Study of Costs and Benefits. Hartridge M, Seeger BR, Assist Technol (in press).

[572] Toward Further Development of a Modular Wheelchair Tray for the Physically Disabled

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Sponsor: *National Health Research and Development Programme, Department of Health and Welfare, Canada*

Purpose—Our purpose is to develop a modular wheelchair tray which meets the therapeutic and communication goals of the clinician and the personal needs of the user and caregiver.

The specific goals are to: 1) develop an upgraded modular wheelchair tray which can be partially tilted to various positions and folded away beside the wheelchair by the caregiver; and, 2) fabricate and assess the performance of the upgraded modular tray.

Progress—Development of a second-generation modular system has focused on creating hygienic, lightweight tray modules which can be customized to accommodate a client's seating insert, as well as the user's communication device and wheelchair control interface when appropriate.

The prototype tray system incorporates a hinged, adjustable distal section, a laminate construction consisting of thin, molded Kydex, and a stiff polycarbonate honeycomb core. To cushion the tray and protect any delicate communication device nested in the tray from inadvertent collisions, an integral lip reinforced with high

density polyethylene is provided. The proximal section is also a laminate but does not have a raised lip at its periphery. This ensures that the folded thickness of the tray is minimized. Hardware attached to the proximal tray and the wheelchair permits the tray to be folded and stored beside the chair without requiring its removal.

Methodology—Seven subjects, 5 to 29 years of age, participated in the clinical field trials which were of no less than 6-weeks' duration.

Results—Results of the evaluations by caregivers suggest that the prototype tray system was well received. The system was found to be durable and safe to use, and the tilt feature appeared to facilitate user access to communication systems. The fold-away option was also found to be useful.

With the provision of a variety of distal tray modules, the production version of the tray is expected to offer a functional arrangement that will closely conform to the needs of most physically disabled persons requiring an augmentative communication system.

[573] Ergonomics of Manual Wheelchair Propulsion

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Sponsor: Innovative Research Programme for the Disabled

Purpose—Manual wheelchair propulsion was studied from a combined physiological and biomechanical perspective, with the general aim of improving the mobility of wheelchair users. A better understanding of factors influencing the work capacity and power output of the wheelchair user, and those factors influencing the wheelchair-user interaction, is fundamental in this respect.

Methodology—Wheelchair propulsion was studied by placing a wheelchair on a motor-driven treadmill and simulating conditions on a computer-controlled wheelchair ergometer. A complete three-dimensional (3-D) reconstruction of the movement pattern was combined with measures of force and power production and electromyography of upper arm and trunk muscles. An inverse dynamic segment model was used to interpret cardiorespiratory phenomena and measures of efficiency from a biomechanical and anatomical perspective.

Progress—Studies have begun on the effectiveness of torque production under various conditions of power output and in different groups of disabled and nondisabled subjects.

Recent Publications Resulting from This Research

Propulsion Technique in Hand Rim Wheelchair Propulsion. Woude LHV van der, Veeger HEJ, Rozendal RH, *J Med Eng Tech* 13:136-141, 1989.

Wheelchair Propulsion Technique at Different Speeds. Veeger HEJ, Woude LHV van der, Rozendal RH, *Scan J Rehabil Med* 21:197-203, 1989.

A Computer Controlled Wheelchair Ergometer. Niesing R et al., *Med Biol Eng Comp* 28:329-338, 1990.

Design of a Static Wheelchair Ergometer: Preliminary Results. Woude LHV van der et al., in *Adapted Physical Activity. Proceedings of Adapted Physical Activity Quarterly, 7th Symposium*, 441-446, Doll-Tepper, Dahms, Doll, Von Selzam (Eds.). Berlin/Heidelberg: Springer Verlag, 1990.

Within-Cycle Characteristics of the Wheelchair Push in Sprinting on a Wheelchair Ergometer. Veeger HEJ, Woude LHV van der, Rozendal RH, *Med Sci Sports Exerc* (in press).

[574] Functional Assessment of the Performance Capacity of the Wheelchair-User Combination in the Course of Rehabilitation

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Sponsor: Innovative Research Programme for the Disabled

Purpose—A protocol will be designed and tested for the functional evaluation of the wheelchair-user combination during the course of rehabilitation. Spinal cord injured subjects will be evaluated repeatedly with the help of this protocol. The predictive value of the protocol with respect to the functional capacity of the future wheelchair user and the wheelchair will be evaluated. Thus, the selection and provision of a given type of wheelchair, at a given stage of rehabilitation, may be determined more accurately.

Methodology—Exercise tests will be performed on a stationary transportable wheelchair ergometer and on a standardized wheelchair track. Heart rate and ECG will

be monitored in conjunction with power output and energy cost. Both a sprint protocol and an aerobic maximum exercise test will be conducted on the ergometer at different stages in the rehabilitation process. The cardiorespiratory stress of several tasks on the wheelchair track will be evaluated similarly.

Progress—Exercise protocols are being tested. The wheelchair track is currently being designed and the stationary wheelchair ergometer is being built. Preliminary data from recent tests (both sprint and max) on a group of 44 male spinal cord injured subjects who completed the rehabilitation program several years before are currently being processed.

[575] Wheelchair Evaluation

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Sponsor: Ministry of Health of Ontario; Royal Ottawa Health Care Group

Purpose—The purpose of this project was to develop equipment and procedures to test wheelchairs prior to their being funded by the Assistive Devices Branch of the Ministry of Health of Ontario. Test procedures have been set up and criteria for acceptance or rejection of new wheelchairs are being established.

Progress/Results—The facilities for testing wheelchairs have been refined and a parallel testing facility has been set up at Victoria Hospital in London, Ontario. The results obtained in the two centers are compared regularly

to ensure that both testing facilities and procedures are operating correctly.

All of our results are being placed on a database which, when added to other data available from organizations such as the International Standards Organization, the Department of Veterans Affairs, the British Standards Institution, etc., will allow us to determine what is acceptable and what is not. A list of necessary criteria for acceptance is being prepared for the manufacturers so that they know what is expected of their products before presenting them for evaluation.

[576] Rehabilitation Engineering Center for Personal Licensed Transportation for Disabled Persons

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The Rehabilitation Engineering Center for Personal Licensed Transportation for Disabled Drivers was established July 1, 1990 by the National Institute on Disability and Rehabilitation Research. The ability to move from place to place rapidly, conveniently, safely, and economically is a prerequisite to full participation in any society. Although both private and public transportation systems exist, private transportation in a personal vehicle is frequently the only means of transportation available for the handicapped person. There are, however, no commonly accepted standards for the adaptation of personal vehicles to accommodate disabled individuals as drivers or passengers. Adaptations may compromise the structural stability and safety of the vehicle, may not provide easy boarding or safe and rapid exit from the vehicle, and may include unsafe or ineffective control devices. Seating systems and systems for securing wheelchairs in the vehicles are often unsafe and ineffective.

The objectives of this Center are to elevate the state-of-the-art technology and knowledge relevant to personal transportation systems to the highest possible level, and to transfer this knowledge and technology to a level of practice that results in optimum utilization. In order to accomplish these objectives, 14 tasks have been defined

within the Center. They are: 1) identify and catalog vehicle safety access and exit systems; 2) assess deficiencies in assistive technology for personal transportation systems; 3) develop methodologies for checking device compliance with existing federal or state standards; 4) develop methodologies for evaluating equipment to be used when assessing individuals' needs for vehicle modifications; 5) develop methodologies to evaluate vehicle access and exit systems for safety and effectiveness; 6) develop and validate methodologies to evaluate and improve the effectiveness of wheelchair tie-downs and occupant restraint systems, and the safety of vehicle structure; 7) develop methodologies for performing structural integrity analysis of vehicle modifications for disabled persons; 8) develop an analytical methodology for evaluating and improving wheelchair tie-downs and occupant restraints; 9) develop protocols for physical tests of vehicle structural modifications for safety; 10) develop protocols for the physical testing of wheelchair tie-downs and occupant restraints for crashworthiness; 11) develop a program for training in these areas; 12) develop a method for dissemination of this information; 13) conduct a state-of-the-art study of personal transportation systems to help direct and plan research

and development activities of the Center; and, 14) to develop improved designs for equipment, devices, and modifications for personal vehicles for disabled individuals.

Implications—The realization of these objectives and tasks will result in optimum matching of vehicles, modifications, safety systems, and adaptive driving devices to the needs of the individual disabled driver. The modifications made to the vehicle will not disrupt the continuity

of load-carrying structures; adaptive devices and safety systems would be ergonomically designed for efficacy of use according to individual requirements; the reliability of modifications, tie-downs, occupant restraints, and adaptive devices will exceed the useful life of vehicles in which they are installed. Finally, the dissemination of information to consumers, service providers, manufacturers, and third-party payers would insure that all disabled individuals with a potential to benefit would have access to the technology and services.

[577] Research on Improving Wheelchair Frame Durability

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The intention of this work is to keep the stress analysis of wheelchair frames at the personal computer level to demonstrate to the designers and manufacturers that high-cost large computing machines are not necessary to perform these types of analyses.

Progress—The work during this last project period consisted of developing finite element (FE) models for both powered and manual wheelchair frames. Detailed FE analyses have been performed on two wheelchair designs, one a conventional cross-frame power model, and the other a single-member side frame "spring" model. Both wheelchair models were developed to improve our understanding of the way occupant loads are transferred to the frame members and to establish the high stress regions in each design. The PAL2 FE code from the MacNeal-Schwendler Corporation was used to perform the calculations. PAL2 was run on an IBM PC-compatible personal computer.

The power wheelchair FE model consisted of 195 tubular elements and 1,046 active equations. The frame was assumed to be constructed from UNS 10100 cold-drawn steel tubes with nominal wall thicknesses of 0.060 inches. The occupant was assumed to weigh 180 pounds and the frame was loaded according to static measurements made at the University of Virginia Rehabilitation Engineering Center (UVA-REC). A maximum von Mises stress of 22,470 pounds per square inch was calculated at the midpoint of either 1.014-inch OD cross brace tube. This particular model was used in conjunction with the work accomplished in the reliability studies.

The spring wheelchair model consisted of a frame tube that was assumed to be constructed from SAE 4130 steel tube with a nominal outside diameter of 1 inch, and a wall thickness of 0.058 inches. The model was composed of 528 quadrilateral plate elements and has 2,600 active degrees-of-freedom after constraint. The single-tube sideframe was modeled carrying half of the assumed 180-pound occupant weight.

Preliminary Results/Future Plans—Two analyses of this structural member were performed. In the first, the 90-pound occupant load was applied equally along the top section of the tube where the seat would rest. It was determined that the maximum von Mises stresses occur at the inside of the 3.5-inch radius bend and have a value of 44,380 pounds per square inch (compression). The tensile stress at the outside of the tube are of similar magnitude. The second analysis determined that the tube structure has a spring constant in the plane of the tube of about 106 pounds per inch. A 90-pound concentrated load applied at the free end produced a vertical deflection of the free end of 0.85 inches.

Because of the model size limitations imposed by PAL2 on dynamic calculations, no dynamic analyses were performed on these two wheelchair models. PAL2 allows only 100 active degrees-of-freedom for dynamic analysis, which is insufficient to model a cross-brace wheelchair structure. We are now seeking other PC-based FE models to accurately model wheelchair frames.

[578] A Wheelchair for Exercising Paralyzed or Paretic Limbs of Paraplegics

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Sponsor: *New York State Science and Program and Technology Foundation (Technology and Disabilities Program)*

Purpose—Electrically-induced exercise of paralyzed or paretic muscle is known to be clinically beneficial, and under experimental conditions, even functional. However, benefits accrue and are maintained only with frequent and habitual exercise. Few persons who are clinically eligible (e.g., whose muscles and final common pathways are intact) for electrically-induced exercise actually receive it for lack of safe, simple, and affordable means. Many of these persons currently use wheelchairs as their primary means of transport; these, however, do nothing to curb further atrophy and may even exacerbate pressure sores, edema, and contractures in lower limbs that are more or less fixed in pendant position. Our purpose, then, is to develop a wheelchair that maintains all standard functions, but also provides a means of frequently and habitually exercising, via electrical stimulation, paralyzed or paretic limbs while the user is engaged in normal daily activities. The exercise is designed to be functional in that it augments propulsion of the wheelchair, although at no time is movement of the wheelchair dependent on that activity.

Methodology—Hand cranks on folding, adjustable towers are bolted to sport model wheelchair frames just in front and to the side of the leading edge of the seat. Hand cranks are lined to reciprocating footglides and rear wheels via belts. Turning both hand cranks forward simultaneously results in movement of the footglides and forward rotation of the rear wheels of the wheelchair. Turning the hand cranks backward disengages the footglides (via a clutch), but drives the rear wheels in reverse. Steering is accomplished by differential use of the hand cranks. A computer senses the position of each footglide, and if a variety of requirements are met (e.g., going forward, within certain speeds, etc.) turns on and off at appropriate times, individual channels of commercially available neuromuscular stimulators. These in turn stimulate muscles that drive the footplates back and

forth. Force produced by the stimulated limbs thereby augments propulsion of the wheelchair. Speed and direction are always under voluntary control of the user; only timing of stimulation is computer-controlled.

Progress—A functioning prototype has evolved from several designs. Mechanical aspects of the prototype have been field-tested and revisions made; electronics are still being bench-tested.

Results—Our prototype maintains all functions of a standard wheelchair (e.g., it folds, fits under a standard desk or table, can be pushed or propelled in the usual fashion), yet can convert to crank mode or from crank mode to standard mode in less than 5 seconds. Steering and braking are simple and effective. Because power is delivered to the rear wheels through 360 degrees of crank rotation, propulsion is far more efficient than standard means, and average cruising speed increased. The wheelchair can be operated in the normal way even when cranks are erected. Although the wheelchair can be pulled into and maintained in "wheelie" position, weight is unacceptably high. The electronics function properly, but need customizing to reduce size and weight.

Future Plans—All components will be brought to commercial grade and the system thoroughly tested for safety and efficacy in clinical and field conditions.

Recent Publications Resulting from This Research

Vehicles for Exercising Paralyzed Limbs. Mendel F, Fish DR, in *Proceedings of the Third International Workshop on Functional Electrostimulation*, Vienna, Austria, 175-188, 1989.

Patents

Hand and Foot Propelled Tricycle for Electrically Inducing Exercise in Paralyzed and Paretic Muscles. F. Mendel, D. Fish, W. Tanski, R. Kell. U.S. Patent Number: 4,863,157; Date of Patent: Sept. 5, 1989.

[579] An Italian Consumer Survey of Wheelchairs

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Sponsor: *The Region of Lombardy*

Purpose—The purpose of this project was to investigate wheelchair use among a large number of consumers, and to integrate the method into the general Servizio Informazioni Valutazione Ausili (SIVA) wheelchair evaluation program.

Methodology—In 1986, an experimental questionnaire was designed and distributed to approximately 100 persons. This experience proved positive, and in 1987 an improved version was distributed. Ten thousand copies were sent all over Italy for a complete consumer survey. Magazines, rehabilitation centers, and associations of disabled persons were involved. During a period of 2 years, about 1,000 questionnaires were returned to SIVA; 731 of them were valid for processing. Special software was designed to process the results. The questionnaires were read and interpreted easily, because preselected answers were used, needing only a confirmation mark. The survey included 45 questions concerning personal data about the consumer, model and type of wheelchair, where and when the wheelchair was used, the consumer's evaluation on various aspects (e.g., mobility, brakes, transfers, maintenance), and general opinions about design and safety.

Results—The survey covered manual and powered wheelchairs for adults, purchased between 1976 and 1987. Twenty-nine trademarks were represented, 11 of them

belonging to foreign companies. The data profiled fairly active wheelchair users, mostly with neurological or muscular diseases, who use their wheelchairs for all purposes. Previous experiences in other wheelchairs were reported so that users were able to compare their wheelchair to other models. In the majority of cases (71%), the wheelchair was prescribed and user cost was reimbursed by the National Health Care system or the insurance company. Fifty percent of the users did not have the opportunity to try the wheelchair before delivery, and 42% said the selection of the model was made by someone else. Breakdowns were shown in 76% of the cases, and one-third of these users reported difficulties in having the wheelchair repaired. Still, 68% of the users concluded that they were satisfied with the wheelchair choice.

Future Plans—This experience, the first in Italy, is the basis for SIVA, and for further research and development of the technical and functional evaluation of wheelchairs. The results support using standardized tests for additional information concerning wheelchair use in the field.

Recent Publications Resulting from This Research

Consumer Evaluation of Wheelchairs. Johnson I, in Proceedings of ECART, Maastricht, The Netherlands, 1990.

A Consumer Survey of Manual and Electrical Wheelchairs for Adults in Italy. Ronchi R, Johnson I, in *Wheelchair Testing: Latest Advancements in Research*, COMAC-BME, EEC, Milan, Italy, 1990.

[580] Investigations into the Influence of Wheel Position on the Propulsion Capabilities of Wheelchair Users

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Sponsor: *Tayside Health Board*

Purpose—Many wheelchair users have only marginal ability to independently propel their wheelchair. Their ability can be enhanced by optimizing the position of the wheelchair wheels. Many wheelchair designs provide the necessary adjustability, but difficulties can be experienced in determining the optimum setting for individuals.

Progress/Methodology—A highly adjustable wheelchair has been developed to simulate the dynamic characteristics of wheelchairs while permitting ready adjustment of the wheel positions. A series of standardized tests and maneuvers have been developed with simple measures of performance. Disabled subjects have conducted these tests for variations in the wheelchair simulator.

Results—The results of these preliminary studies have shown that the methodology can detect the influence on propelling performance of wheel position in both vertical and horizontal displacements. The results are generally in agreement with those of other studies using static dynamometers.

Future Plans—Further funding is being requested to expand this project to incorporate larger numbers of

subjects. It is intended to determine more clearly the influence of wheel position and include other variables such as wheel diameter, handrim diameter, and castor configuration.

A simplified wheelchair simulator and test procedures are to be developed for use as routine clinical tools for optimizing wheelchair configurations for individual people.

[581] Comparative Evaluation of Chargers for Wheelchair Gel Cell Batteries

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Sponsor: *None listed*

Purpose—This study was undertaken as part of our ongoing work to upgrade wheelchair quality. Our purpose was to compare the commercial battery chargers available in Australia for Sonnenschein A200 24 Ah and 36 Ah gel cells in order to determine which of them would be the best value for our clients.

Methodology—Laboratory tests were conducted to determine which battery chargers would ensure that the users' batteries were fully charged each night, and also ensure that the battery lifetime was not diminished. Five commercial chargers were tested on a standardized pair of Sonnenschein gel cell batteries. We developed a battery charger test facility which enabled us to monitor the maximum case temperature during charging, energy from the batteries, efficiency of energy transfer, sensitivity to main voltage fluctuations, direct current, ripple current, peak charge voltage, and typical charging characteristics. We also compared purchase price, size, mass, whether the suitable battery type was clearly marked, safety factors (reverse polarity protection and short-circuit protection), indicator lights, and human factors.

Results—Results of this study have indicated a clear preference between chargers, although none of the chargers conforms to the battery manufacturer's specifications.

Implications—As a result of this research, we have changed the chargers we purchase. We anticipate that our clients will now experience longer life from their wheelchair gel cell batteries. We have also identified a need for a 6 A DC-style battery charger to ensure that the charge time for 36 Ah batteries is of the order of 8 hours, corresponding to a full recharge overnight.

Another benefit of this research is that some manufacturers are now upgrading their products with the assistance of our testing laboratory.

Recent Publications Resulting from This Research

Comparative Evaluation of Chargers for Wheelchair Gel Cell Batteries. Garrett RE, Hartridge M, Seeger BR, *Australas Phys Eng Sci Med* 13(3) (in press).

B. Powered Controllers

[582] Linear Synchronous Motors for Power Wheelchairs

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Sponsor: VA Rehabilitation Research and Development Service (Project #B338-4RA)

Purpose—The purpose of this project is to develop a highly efficient direct drive axial flux motor for powered wheelchairs. The lightweight motor (about 23 lbs) will fit inside a 14 × 2 inch wheel with stall torque of 35 pound-feet and an average efficiency of about 80%. An additional goal is to minimize the “cogging” which causes motors of this type to “stick” in certain locations, thus increasing vibrations and losses in power.

Methodology—Based on current findings in motor research, a promising motor design idea was constructed. This design was coined a Linear Synchronous Motor (LSM). The prototype verified the workability of the initial design idea, given certain modifications in geometry and placement of magnetic materials. The design method was then chosen to be a combination of computer modeling and physical modeling of certain parts of the motor. The process was then repeated until the project goals were met.

A simple microprocessor-based controller was developed using a HP development system to run the prototypes. A refined controller will be developed in conjunction with the final prototype to meet the project goals.

Progress—Two prototypes have been constructed and tested in addition to the five prototypes constructed in the previous year. A microprocessor-based controller (based on the 6809 microprocessor) has been designed and implemented. A third prototype has been designed and is now being constructed.

A three-dimensional finite element modeling software package has been evaluated and ordered to be used for the computer modeling of the motor to give more precise predictions. An upgrade for the HP 9000 minicomputer has also been ordered to run the software.

Preliminary Results—The full testing of the first prototype of 1990 revealed one remaining problem in achieving our goals. The efficiency and torque were achieved but a considerable amount of cogging still remained. This led the engineers to design another prototype after a considerable amount of testing from a “jig” that simulated pieces of the motor. This prototype dramatically reduced the cogging while keeping the other goals attainable. The difference between this prototype and the first is in the orientation of magnets and teeth.

The second prototype was then modeled by computer to determine the optimum size of magnets and spacing of the air gap. Better magnetic materials were chosen for the design of the next prototype.

The third prototype is being constructed and should minimize the cogging torque.

Future Plans/Implications—A “low cost” version of the system will be constructed using inexpensive ceramic magnets and will be evaluated. Other versions will be designed and constructed to determine an optimum configuration for the limits of the system. The controller will be refined to include a digital signal processing chip which will provide intelligent control of efficiency and wheel motion.

[583] Ultrasonic Head-Controlled Wheelchair and Interface

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Sponsor: *VA Rehabilitation Research and Development Service (Core Funds); Paralyzed Veterans of America*

Purpose—The Ultrasonic Head Control Interface (UHCI) is a device designed to provide severely disabled individuals (quadriplegics) with a means of controlling devices, such as electric wheelchairs, in a socially acceptable and aesthetically pleasing manner.

Progress/Methodology—In this project, two Polaroid ultrasonic distance ranging sensors are the basis for a new type of human-machine interface. They emit inaudible high-frequency sound waves which propagate through the air until reflected by an object. A portion of the signal incident on the object is reflected as an echo and is detected by an electronic system. The elapsed time from transmission of the signal to the reception of its echo is proportional to the round-trip distance from the sensor to the object. In this rehabilitation application, two separated sensors are directed at the head of the user. The two resultant distance ranges, one from each sensor to the head, and the fixed distance between the stationary sensors describe a triangle whose vertices are the two sensors and the current head position of the user. A geometric relationship allows the offset from the baseline and center-line of the two sensors to be calculated. The array of distance-ranging sensors can monitor the head position of a severely disabled quadriplegic operator to obtain command and control information for the operation of mobility, communication, and robotic devices.

In operation, the user of an UHCI merely tilts the head off the vertical axis in the forward/backward or left/right directions. The translation of head position information into electrical signals can mimic the output of a joystick. Both can be used to control devices to which they are attached, such as a wheelchair, a communication aid, a video game, or a robotic arm.

Preliminary Results—Within the VA Rehabilitation Research and Development Service (RR&D), UHCI have been installed on two electric wheelchairs. The first is an Everest & Jennings model 3P equipped with a reclining Recaro seat and is in use in France by a quadriplegic woman. The second, mounted on an Invacare Rolls IV with a Solo Products Power Pack, continues to be demon-

strated at RR&D and evaluated by spinal cord injury patients at this VA facility.

Both units have been operational since June 1983. User evaluation has been performed with 10 quadriplegic individuals. After a short demonstration and training session, they were transferred into the chair and most were able to successfully navigate the chair without problem. Users stated that they preferred the ultrasonic head control to the chin-controlled joystick wheelchairs they had used. The device has proven to be easy to use. Its intuitive operation requires little focused concentration and thus does not result in user fatigue.

Funding for the construction and testing of four commercial prototype UHCI equipped wheelchairs has been received from the VA Rehabilitation Evaluation Unit in Baltimore. Eureka Laboratories of Sacramento was competitively selected to manufacture these devices. The first unit is currently undergoing human subject evaluation at the VA Medical Center in Richmond. After this first pilot study, the evaluation program will continue at VA Centers in Augusta, Houston, and Tampa.

Future Plans/Implications—The evaluations have been completed and a final report is to be published. That document will summarize the results of the study and contain a recommendation regarding the prescription of electric wheelchairs using the UHCI technology for appropriate severely disabled veterans. If an approval is forthcoming, Eureka Laboratories has indicated that they will pursue mass production of the UHCI to satisfy the demand of the VA and other potential purchasers.

A Request for Evaluation was written in response to a request from the Rehabilitation Evaluation Unit in order that they may use the UHCI for computer access applications.

Recent Publications Resulting from This Research

- A Case Study: The Ultrasonic Head Controlled Wheelchair and Interface. Jaffe DL, OnCenter—Tech Trans News 1(2), 1990.
- Ultrasonic Head Controlled Wheelchair/Interface: A Case Study in Development and Technology Transfer. Jaffe DL, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 23-24, 1990.

[584] Electric Wheelchair Controllers: Effect of Speed and Acceleration on Driving Performance

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Sponsor: Channel 7 Children's Medical Research Foundation of S. Australia

Purpose—The purposes of this study are to: 1) determine if adjustable wheelchair control parameters actually improve wheelchair driving performance of children with cerebral palsy; and, 2) determine a procedure for adjusting wheelchair controller speed and acceleration to obtain optimum driving performance. The outcome will be a protocol for establishing optimum controller settings in order to maximize benefits to users of electric wheelchairs.

Progress—A number of subjects with cerebral palsy began trials in August 1990 using a wheelchair and a standard wheelchair joystick augmented to incorporate independent settings for maximum speed and acceleration. The controller utilizes velocity feedback from optical shaft encoders fitted to each motor.

A standard test track incorporating a number of driving tasks has been developed. This allows a grading of the driving task to accommodate a range of competence levels.

Methodology—There are several phases in the experimental protocol.

Baseline. The clients perform a series of circuits of the test track in their own electric wheelchair from which lap times and errors are recorded. The client's wheelchair is then measured for speed and acceleration and these settings applied to the trial chair. The client then performs a similar number of baseline trials using the trial wheelchair.

Optimization of Speed and Acceleration. The client is seated in the trial wheelchair, speed set to minimum, and acceleration varied through five settings, with two laps at each setting. The optimal setting to produce the fastest lap time is then decided upon. This setting of acceleration is used and the speed is varied through five settings for two laps at each setting, and an indication of optimum speed can be gained. This iterative process continues until an optimum setting of speed and acceleration is achieved.

Comparison of Optimum with Baseline. This optimum value of speed and acceleration is then compared in an alternating treatment design with a value of speed and acceleration which approximates that of the controller currently used by the subject. This process will allow us to determine if the optimum setting of speed and acceleration does in fact provide a significant improvement in driving performance.

Implications—The variable parameters of microprocessor-based electric wheelchair controllers are often poorly understood and used by clinicians. This project will provide a standard procedure by which these parameters can be optimized.

Future Plans—Client trials and final report were completed in December 1990.

[585] Isometric Joystick Versus Displacement Joystick for Simulated Wheelchair Control

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Purpose—The purpose of this study was to evaluate the performance of children and adolescents with cerebral palsy using an isometric joystick and compare it with their use of a displacement joystick.

Methodology—The experiment was conducted in two phases. The first phase was designed to give the subjects practice using the isometric joystick and to determine the most appropriate sensitivity setting for the client. This

phase consisted of 15 sessions at which 5 sensitivity settings were presented in random order. These settings were selected to correspond to 25%, 50%, 100%, 200%, and 400% of the force required to give maximum deflection of the standard displacement joystick. At each sensitivity setting, the subject had to complete three trials of four targets on the Skill Evaluator and Trainer—an input device evaluation apparatus that we developed.

Following these sessions, the most appropriate setting for the subject was chosen depending on performance (response time and number of errors) and the client's personal preference.

The second phase of the research involved an alternating treatment design using the conventional displacement joystick and the isometric joystick at the subject's preferred setting. Subjects attended 15 sessions at which the joysticks were presented randomly, 1-minute practice allowed, and then three trials of four targets were completed.

Preliminary Results—A pilot study involving a nondisabled adult has been completed. This was followed by an evaluation of six subjects (five adolescents and one child), three of whom have athetoid cerebral palsy, and three with spastic cerebral palsy. These have been completed and the final data are now being evaluated.

Results for the nondisabled pilot subject indicate a clear preference for the displacement joystick. Two other subjects have completed the trials. One with spastic quadriplegia and previous experience using a displacement joystick to control her wheelchair demonstrated a clear preference for the displacement joystick in the trials. The second subject (with athetoid quadriplegia), who uses foot switches to control his wheelchair, demonstrated a preference for the displacement joystick, but it was not a marked difference. All subjects who have completed trials on the first phase of the project have shown better performance using the heavier sensitivity settings. Two of the four subjects have used Setting Five (four times the amount of force needed to operate the displacement joystick) and one used Setting Four (twice the force required to operate the displacement joystick).

Five subjects began experimental trials in July 1990 and one other began in August 1990. All trials were scheduled for completion by October 1990 and a report was to be written shortly thereafter.

Implications—The isometric joystick has a great deal of face validity as a tool for clients with cerebral palsy. This project will provide empirical data to evaluate its use.

[586] Evaluation of the MANUS Wheelchair-Mounted Manipulator in the Home, Work, and School Environment

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Sponsor: *National Health Research and Development Programme, Department of Health and Welfare, Canada; Rick Hansen Man-in-Motion Legacy Fund*

Purpose—The objectives of this two-year project are to: 1) evaluate an advanced model of a wheelchair-mounted robotic manipulator arm in two settings—an independent living and vocational environment of adults who are physically disabled, and a classroom in a school for physically challenged children; 2) determine the nature and types of activities a user would wish to be able to perform with the help of a manipulator arm; 3) analyze the control commands in order to extract common command sequences that define distinct movements of the arm and/or gripper (e.g., move up and grasp, grasp and turn, fold arm, high reach, and other more functional activities); and, 4) cooperate with the designers of the manipulator system to develop and implement an advanced

control system to increase the efficiency with which persons can use the system.

Methodology—The MANUS project plans to follow six adults and six children as they use the MANUS for their daily activities and structured tasks. A camera system will be used to document actions carried out and joystick commands issued by the user to control the MANUS.

Progress—The project commenced in July 1990 using a prototype model of the MANUS arm. One subject is currently evaluating the system, and two subjects who are ventilator-dependent will begin training shortly.

[587] Adaptive Speed Control for Electric Wheelchairs

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose/Progress—A microcomputer-based adaptive speed control for electric wheelchairs had been developed and implemented at the University of Virginia Rehabilitation and Engineering Center over a period of several years. The system was based in the Z80 microprocessor which had become obsolete.

The system has been updated using an 8086-based microcomputer. The single board computer used—the LPM SBC V40 microcomputer—was chosen for several reasons: it is 16-bit, it has on-board memory, dual serial I/O, counter/timer, and several other features which the Z80 lacked. In addition, it has a speed twice that of the Z80 and is IBM/AT-compatible, thus simplifying program modifications and data transfer to the host for

analysis (during development or updating of control software).

To make the system state-of-the-art, new features have been added, such as an ultrasonic obstacle detector (as a safety enhancement), and a tiltometer to stop the chair operation if it reaches dangerous tilt-speed combinations, etc. The control program itself has been improved to decrease the chance of malfunction. The error terms (i.e., the difference between the commanded speed and the actual speed) controls the command to the motor; a significant improvement stops the chair automatically when the error terms reaches a dangerous level.

The system has been installed in an Everest & Jennings chair and tests have been conducted with satisfactory results.

[588] An Improved DC-DC Converter

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose/Progress—The University of Virginia Rehabilitation and Engineering Center has been investigating dc-dc converters (the electronic device that produces a variable magnitude dc voltage from the fixed 24 volts battery voltage) for several years. The most important characteristic of a good dc-dc converter, in addition to high reliability, must be high efficiency, in order to maximize chair operation before battery recharge. The previous version of the dc-dc converter that was designed, constructed, and tested at the Center satisfied the above characteristics and was

all-solid-state, but used both n-channel and p-channel power transistors, an undesirable necessity. The recent availability of new integrated circuits, namely the IR2110, has made it possible to use n-channel power transistors only. This improves efficiency, reduces the component count and consequently increases reliability.

The new dc-dc converter has been tested and installed in an Everest & Jennings wheelchair with an improved adaptive controller. The chair has been tested in the field with very satisfactory results.

[589] Brushless DC Motor Evaluation

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose/Progress—Traditionally, electric wheelchair propulsion systems have used permanent magnet (pm) direct current (dc) servomotors. These motors use a commutator to reverse the armature winding polarity as the

motor rotates. In spite of their excellent torque/speed characteristics and relatively good efficiency, pm-dc motors require significant maintenance because the carbon brushes used to make contact with the commutator

wear out and have to be replaced. The commutator itself suffers the same problem, at a slower rate.

A relatively new type of dc-pm motor without a commutator is now commonly available. In this motor, the pm is in the rotor, and the armature windings are fixed in the stator. Commutation is achieved by electronic means, instead of a mechanical device. The use of modern integrated circuits for this purpose has several virtues: the circuit is very reliable, practically maintenance-free and

simple. It is also inexpensive. The motor itself, due to its lack of mechanical parts (except the bearings), is very long-lasting and comparable, in this respect, to the ac induction motor. The electronic controller-driver is simple and has very high efficiency. We have evaluated the characteristics and performance of brushless dc-pm motors and found them satisfactory for wheelchair propulsion. We are now evaluating the performance of the motors installed in an electric wheelchair.

[590] Reliable, Available, and Safe Electric Wheelchairs

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The overall objective of this research effort is the application of state-of-the-art engineering techniques to the development of safe and highly available powered wheelchair systems. Although the development process consists of numerous distinct efforts, the ultimate goal is the development of a prototype of the next generation powered wheelchair. The new design will experience fewer repairs, less down-time, and safer operation.

Methodology—The actual effort is broken into five phases: dependability analysis (measured in terms of reliability, availability, and safety), frame and tire durability modeling, system study, bench prototype of system components, and powered wheelchair prototype. Results to date fall into two areas: analysis tools and implementation.

A unique personal computer-based dependability analysis software system, written in C and using a VGA color display, has been developed for the analysis of wheelchair systems. Models of systems containing both

electronic and mechanical components are possible. The analysis algorithms are based on Markov model representations which are either prestored in a library or can be easily entered by the designer. A novel technique for structural reliability analysis, based on random vibration analysis, which results in a failure density function for the structure, has been developed. This new technique provides the ability to generate a Markov model for the structure, which can then be incorporated into the wheelchair system model.

Progress—Initial implementation of the prototype has begun through the development of an architecture (and prototype) for a fault-tolerant dc-dc converter. Reliability and cost analyses of numerous configurations based on complementary metal oxide semiconductor (CMOS) power devices were conducted. A new design which uses two additional transistors, only n-type devices, and passive redundancy to improve reliability was selected for inclusion in the new wheelchair controller.

[591] Research on Wheelchair Frame Modeling

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The effort to improve the modeling of wheelchair frames has centered on developing techniques for assessing the accumulation of fatigue damage in the metal structure and incorporating the method into the wheel-

chair system reliability analysis system that has been under development at the University of Virginia Rehabilitation Engineering Center (UVA-REC) for the past several years. The structural reliability analysis computations are

in a form that can now be directly integrated into the Markov models used to determine the overall reliability of the power wheelchair system.

The wheelchair frame reliability problem can be stated as: "given that the loads acting on the wheelchair frame vary randomly and cause randomly varying states of stress and strain in the structure, and given that the pertinent material properties used in a fatigue analysis are known to be random-valued quantities, and given that the accumulation of fatigue damage in nominally identical structures varies randomly, determine the probability that a structure has not failed a given time in the future."

A solution to the fully random fatigue problem has not been achieved at this time. The solution procedure developed here employs the simplest fatigue damage accumulation model and the most tractable model for the time-dependent structural strain random process and assumes that the material ultimate strength is a random variable. The result is a closed form statement of the probability density function of time to failure of a given structural detail.

If we assume that the accumulation of fatigue damage in a metal structure is adequately described by a S-N curve that is linear in log-log coordinates and the Palmgren-Miner linear damage rule, and that the time history of the strains at any given point in the structure is adequately described by a stationary narrow-band Gaussian random process, the probability density function for the time to failure of the structural detail can be described.

The statistical natures of the material ultimate strength and the stress occurring at a given point in the structure are accounted for in the statistics of the S-N curve parameters. The variability of the stress acting within the structure is the result of statistical variations in the member dimensions (i.e., tube diameters), variations in the loads acting on the structure (i.e., weight of wheelchair occupant), and of variability in the value of the material's modulus of elasticity. To simplify the analysis, all of these parameters are assumed to be normally distributed and the algebra of normal variables is used to derive the expressions for the statistics of the S-N curve parameters.

Results—In order to demonstrate the structural reliability calculations, a finite element model of a standard folding frame electric wheelchair was analyzed. The highest von Mises stress point was found to be in the cross tubes at the point where they cross; the maximum stress calculated was 22,470 psi. The through hole in the tube causes a static stress concentration factor of 3.924.

Using the statistics for the large diameter tubes, occupant weight, and modulus of elasticity listed above, the standard deviation of the static stress at any point in the structure was calculated by perturbing each random design parameter in turn, and determining the variation in stress caused by each perturbation. For the power wheelchair under consideration, the standard deviation of the stress at the cross brace connection point was calculated to be 2,426.7 psi.

With the statistics of the pertinent design parameters known, the evaluation of the probability density function was performed, thereby giving a failure rate. The failure rate does not follow the classical "bathtub" curve typically assumed in electrical and electronic reliability studies. The failure rate for the structural component consists of a period of essentially zero failures, a period of nearly linear increase, and a period of rapidly rising value. The monotonically increasing failure rate is what would be expected from a metal component undergoing fatigue damage accumulation over time.

The method developed for assessing structural reliability under random loading is straightforward to apply and can provide a useful measure against which to compare competing structural designs. Because of the simplifying assumptions incorporated in the analysis, the computed values of structural reliability may be subject to some error; the value of the method lies in its simplicity and its ability to provide a measure of merit for structural design.

Recent Publications Resulting from This Research

Structural Reliability Analysis of Power Wheelchair Frames.
Baldwin JD, Masters thesis, University of Virginia, 1990.

[592] The MIT Damped Joystick: A Control Interface for Tremor-Disabled People

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Sponsor: *National Institute on Disability and Rehabilitation Research; Burke Rehabilitation Center*

Purpose—The intention tremor or cerebellar ataxia often seen in people with multiple sclerosis and head injury precludes independent motor activities of many kinds. In particular, use of joystick-controlled powered wheelchairs is commonly ruled out because of unacceptable inaccuracy of steering and speed control caused by the tremor. While several available chairs include electronic filtering as a feature, this has disadvantages, including failure to deal with the visible shaking of the user's hand. To deal with this problem, the tremor group in the Newman Lab has developed a joystick which incorporates viscous damping. It does so by means of a simple chamber of 2,500,000 centistoke silicone grease through which an extension on the joystick shaft moves as the joystick handle is moved. One hypothesis is that unlike downstream filtering, this energy-dissipating load will have a compensator-like effect on the neural control loops generating tremor so that the oscillatory muscle torques driving the tremor will be reduced rather than opposed.

Progress—Objective tests have been conducted in video tracking and "driving" tasks with a small number of tremor-disabled subjects. The results showed statistically and clinically significant reduction in tremor and improvement in signal-to-noise ratio. Some of the data indicated that an optimal level of damping had been found at an intermediate value between the maximum and

the minimum to which the joystick can be set. Subject reactions to the joystick have been highly favorable.

Future Plans/Implications—A protocol has been developed for simple clinical evaluation of wheelchair driving skill using the joystick. This experimental plan involves measurement of a "Fitts' constant," relating the required accuracy of steering task to the speed with which it is performed. It is hypothesized that this constant will be improved by the optimal amount of damping (i.e., that for a required accuracy, greater speed will be possible).

A third iteration of the joystick design is being prepared which will provide the same adjustability as the present unit in a smaller package. The new version will also permit easy exchange of handles for different users, and will improve ease of manufacturing.

Recent Publications Resulting from This Research

Evaluation of a Damped Joystick for People Disabled by Intention Tremor. Beringhause S, Rosen MJ, Huang S, in Proceedings of the 12th Annual RESNA Conference, New Orleans, 40-41, 1989.

Patents

Tremor Suppressing Hand Controls. Michael J. Rosen; assignee: MIT. Patent Number: 4,689,449; Date of Patent: August 25, 1987.
Multiple Degree of Freedom Damped Hand Controls. Michael J. Rosen; assignee: MIT. Application Number: 444,540; Patent applied for: December 1, 1989.

[593] Development of a Smart Wheelchair

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Sponsor: *National Research Council of Canada, Institute for Intelligent Systems*

Purpose—This effort is directed toward improving the navigability and safety of powered wheelchairs. Of particular interest are techniques that make powered wheelchairs easier to use. New developments in this area will make powered mobility accessible to those who have both motor and sensory disabilities.

Methodology—A network of interested parties has been assembled to work on various aspects of this problem. The network includes: Hugh MacMillan Rehabilitation Centre (HMRC), Toronto; Bloorview Children's Hospital, Toronto; Everest & Jennings Canadian Ltd. (E&J), Concord, Ontario; and other interested parties. A survey

of current users of powered wheelchairs, plus potential users of sensor-enhanced wheelchairs, is underway at the HMRC (under contract from NRC). The aim of this survey is to determine the most serious problems with existing powered wheelchairs, and to find the most appropriate enhancements. The survey will cover a variety of client populations, including the physically handicapped, developmentally delayed, sensory impaired, and elderly, as well as prescribers of mobility aids. It will also attempt to determine the problems encountered by users of powered wheelchairs in a variety of transportation settings.

A basic requirement for the enhanced powered wheelchair is the ability to sense the environment. To accommodate this function, an obstacle detection and odometry subsystem which can be attached to a conventional powered wheelchair is under development. The system will provide a flexible set of intelligent sensors (self-testing and diagnosing) that can be attached at different locations on the wheelchair. A separate controller operates each sensor and communicates with a master controller. These sensors will provide basic obstacle detection and navigational improvements for the powered wheelchair.

To test concepts for the smart wheelchair, a laboratory development system has been established. The vehicle

used is a Cybermation K2A Platform (3-wheeled, synchronous drive and steering, two DC motors). A key element in the development system is a multiprocessor VME computer system, running under a multitasking, multiprocessor operating system called Harmony. Two types of range sensors are currently used on the platform: a sonar sensor system consisting of 24 polaroid ultrasonic sensors arranged in an even radial pattern around the Cybermation platform and a laser ranging system.

Recent Publications Resulting from This Research

Exploration of Robotic Applications in a Long-Term Health Care Setting. Turpin BAM, Korba L, Nelson PJ, Joly R, in Proceedings of the International Advanced Robotics Programme First Workshop on Domestic Robots and Second Workshop on Medical and Healthcare Robotics, Newcastle-Upon-Tyne, UK, 337-339, 1989.

Development of a Wheelchair Controller: Conversion To a Microcontroller. Korba L, Park G, Farley R, Durie N, Roy OZ, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 199-200, 1990.

The Smart Wheelchair: A Discussion of the Promises and Pitfalls. Nelson PJ, Verburg G, Gibney D, Korba L, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 307-308, 1990.

"REDY": An Architecture for a Sensor-Based Mobile Platform. Liscano R, Green D, Canadian Conference on Electrical and Computer Engineering, Ottawa, Ontario (in press).

[594] Identification of Desirable Features of a Smart Wheelchair

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Sponsor: *National Research Council of Canada, Medical Engineering Section (D.E.E. Laboratory for Biomedical Engineering); Everest and Jennings Canadian, Ltd.*

Purpose—This is a collaborative research and development project on the "Smart Wheelchair." Researchers are engaged in a study of powered wheelchairs to determine which smart features are most needed by persons with particular disabilities. A smart wheelchair is any powered chair or scooter which has been augmented with robotic-like sensors, and additional hardware and/or software, so that the resulting system is safer and easier to operate when compared to a conventional wheelchair. Part of this study consists of a survey that will address: 1) problems experienced with current powered wheelchairs; 2) problems encountered in traveling with powered wheelchairs; and, 3) features required in a smart wheelchair to resolve these problems and increase the usability of wheelchairs.

Progress/Methodology—Before surveying users and prescribers of powered chairs, the researchers performed a literature review of research in, and surveys about, wheelchairs and smart wheelchairs. Focus groups were organized and attended by wheelchair users, prescribers, engineers, and project staff. The groups identified issues and features for inclusion in a survey to be mailed to approximately 350 users and 150 prescribers of powered chairs. This paper concerns the results of the focus group meetings.

As of Fall 1990, two survey forms were completed, one for wheelchair users and another for prescribers, dealers, and vendors of wheelchairs. Eight hundred and fifty user-surveys have been distributed across Canada, and 200 prescribers and 150 dealer/vendor surveys have been sent out.

Five focus groups were held, each with a different group of users and clinicians. Forty persons attended the sessions. Fourteen people used a powered wheelchair, 17 were prescribers, developers, or manufacturers (occupational therapists, engineers, clinicians), and five were government officials. The first four focus groups addressed mobility needs of four distinct populations of disabled individuals (i.e., persons who are physically disabled, developmentally delayed, elderly, and persons who are visually impaired or blind). Participants of the fifth group discussed transportation issues.

All participants in the focus groups received three lists of issues pertaining to problems with powered chairs, transportation, and a list of potential smart features. During the focus group sessions, each participant was asked to address each list of topics for 5 to 10 minutes. At the end of the first four meetings, participants were asked to prioritize the issues that concerned them most. Group discussions occurred in which staff members participated and recorded the issues raised. The

compiled notes give an initial indication of the issues of concern and of the desired smart features.

Results—The three lists of issues, compiled from the literature, consisted of 180 items in the above-mentioned categories of “problems with powered chairs” (120), “problems with transportation” (2), and “smart features” (40). The extreme difference in these numbers reflects the amount of attention given to chairs in general, compared to that given to published material on the smart wheelchair, or about the transportation of powered chairs. Literature on the smart wheelchair is relatively scarce due to the novelty of the concept and the limited extent of commercial implementation. The issues regarding transportation often revolve around two or three explicit problems of long standing (i.e., tie-down systems in buses, chair and battery transportation on planes, and accessibility of public transportation). A distinction is made between smart and traditional features, corresponding to smart and traditional chairs.

[595] Further Development and Clinical Testing of a Multifunction Vehicular Interface Unit for Quadriplegic Drivers

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Sponsor: Ontario Ministry of Transportation and Communications

Purpose—The objective of this project is the further development of an interface unit which provides physically impaired persons with access to secondary vehicular functions (i.e., turn signals, horn, wipers, etc.) and to evaluate the person's ability to operate the system under simulated driving conditions.

Driving allows physically impaired individuals freedom of movement within the community—freedom to pursue educational, social, vocational, and recreational pursuits. Alternate forms of public transportation often do not allow for this independence.

Commercial systems exist that allow for adaptations to a vehicle's steering, braking, and acceleration systems, as well as some secondary functions. However, drivers who use these aids indicated the need to have alternative means of access to additional secondary functions that present systems cannot be adapted to provide.

The Hugh MacMillan Rehabilitation Centre received funding to develop a multifunction vehicular interface unit for quadriplegic drivers. This interface unit pro-

vides the driver with access to 54 secondary vehicular functions.

Methodology—To adhere to a new alternate access system model developed within the Centre's Microcomputer Applications Programme, a modular approach has been taken in the software design stages. The scope of changes required a redesign of the interface system. The software was written in the programming language C in a style wherein both the structure of functions and the calling of functions meet the model's guidelines. Thus, the system provides support for a wide number and combination of input devices and output functions.

To provide ready flexibility in the creation or customizing of a control panel's appearance and operation, a graphics-based development system has been created to run on the IBM personal computer family. This configuration facility allows for the development of the access system. The number and type of input switches can be defined, as well as the placement of the output indicators

displayed as objects on the screen. These can be labeled and located according to priority of use. Attributes of all input and output objects (i.e., momentary and alternate action) can also be defined. Scanning paths can be described to best meet each operator's abilities.

Functions to be accessed are grouped according to priority of use (i.e., windshield wipers have more priority than door locks) as well as to the user's preference. Access to functions are provided through a minimum of three switches in combination with scanning, by direct selection of individual functions if switch sites accessible by the user are available, and by direct switch selection to all 54 functions displayed on a control panel.

Results—A prototype has been developed that includes a 54-function access method system based on a STD-BUS controller and a configuration development system. This provides a simple modular approach to the hardware, allowing for ease of customizing to the user's access requirements. The hardware also satisfies the extended temperature range required for operating in an all-weather vehicle (−40 through +85 degrees C).

Future Plans—The next stage of this project calls for clinical evaluation of the interface under simulated driving conditions. This evaluation focuses on the user's ability to operate a scanning technique while operating a vehicle, and to identify other needs of the physically impaired driver.

[596] Effects of Flexible Passive Standing in Patients with Spinal Cord Injuries

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Sponsor: RETEC U.S.A., Inc.

Purpose—The purpose of this study is to examine the effect of a specially constructed wheelchair (the HiRider) for persons with severe physical limitations. The HiRider is designed to allow patients confined to a wheelchair to attain unassisted passive standing. The study has three major components: 1) the impact on physiological factors such as bowel and bladder function; 2) the use of the device throughout an individual's acute rehabilitation; and, 3) the impact of the HiRider in an employment setting. Different methods and different subjects will be used in each component: 1) single-subject research design; 2) intensive case study with several standardized assessments and interviews; and, 3) case study with one standard assessment, self-reports and interviews.

Methodology—*Component 1. Physiological Effects: Single-Subject Research Design.* A single-subject experimental design will be used to compare the HiRider and a standard wheelchair; the design selected is the non-concurrent multiple baseline across subjects. It will include reversal phases to increase the inferential confidence associated with any positive (or negative) outcomes. This design is intended for use in settings where several patients with similar characteristics are not simultaneously available. Three similar subjects will be randomly assigned a predetermined baseline period, followed by alternately introducing and withdrawing the intervention.

The baseline (B) condition involves use of the patient's standard wheelchair. In the intervention (C) phase, the standard chair is replaced with the HiRider for 3 weeks. The initial B phase for each patient varies from 5 to 15 days, and is randomly assigned to the patients as they become available. All subsequent B phases are 3 weeks in length.

Three subjects are participating in this study. They meet the following criteria: 1) spinal cord injury between C6 and T12; 2) currently completing inpatient rehabilitation program; 3) male; 4) between 15-40 years of age; and, 5) medically stable.

During baseline, the patient continues to use his standard wheelchair, and information on the following outcome measures is recorded:

Blood Pressure. Blood pressure is recorded on a daily basis.

Arterial Blood Oxygenation. The Pulse Oximeter (Ohmeda, model 3760) is used to collect information concerning pulse rate and arterial oxygen saturation.

Bladder Function. The volume of urine discharged at each catheterization is recorded.

Bowel Function. The frequency of bowel movements is recorded in the patient's chart across all phases of the study.

Decubitus. Inspection for unusual or abnormal skin redness (nonblanchable erythema, a precursor to decubitus)

is conducted and recorded. The recording consists of a simple yes/no judgment.

Muscle Atrophy. Two measurements of muscle bulk on each leg are taken daily.

The outcome measures are recorded consistently across all phases of the design. In the C phase, the patient begins using the HiRider for 3 weeks; at that time the chairs are switched again and the patient returns to his standard chair. The outcome measures continue to be recorded as in the (B) phase.

Data from all primary (repeated) measures will be graphically presented and visually analyzed. Celeration lines will be computed as adjuncts to visual analysis to help identify trends within and across phases for a single subject. In addition, a randomization test will be computed for all primary (physiological) measures to statistically analyze data from replicated ABAB designs across independent subjects.

Component 2. Impact on Acute Rehabilitation. One subject will be studied in an intensive case study approach, providing a descriptive analysis of the impact of the HiRider during an individual's acute phase of rehabilitation—up to the point of discharge. Measures will be taken on a scheduled basis; the patient will be interviewed three times each week. The subject will receive training on the use of the HiRider, and for the first month will be left on his own to determine how often he uses it, and how much he uses it in the standing position. If, after the first month, the amount of standing time appears inadequate, the subject will be counseled on the importance of standing and given a recommended schedule. There are four measures to be taken: 1) device utilization; 2) physiological areas; 3) psychological; and, 4) other.

We will determine how often the HiRider is used in the standing position, the seated position, and in both

(horizontal) motion, and in stationary position and distance traveled. This information will be examined against the physiological, psychological, and activity level measures, and related to the interviews. The interviews will be structured to follow up with questions on device use that relate to distance (where traveled), and standing (what did you do in the standing position), energy expenditure, and age equivalent, and estimates of potential and current oxygen consumption.

Component 3. Impact on Employment. The ICD Survey of Disabled Americans (1986) found that 67% of working age individuals with disabilities were not working, even though most expressed an interest in working. The HiRider has the potential to increase a person's ability to complete work-related tasks.

Future Plans/Implications—This case study will examine the impact of the HiRider on a person confined to a wheelchair. A HiRider will be placed in the person's work setting for him to use while on the job. Device utilization will provide a baseline of information on how often the HiRider was used, how far it traveled, and the amount of time it was used in standing versus seated position. Several measures will be taken routinely, including hours worked, quantity of work, ease of completing tasks, fatigue, and stress. Stress will be measured with the Occupational Stress Inventory, a standardized assessment. The other measures will be taken with a self-report form. To validate the self-report measures, a therapist will do monthly interviews covering the same areas, as well as additional questions on use of the HiRider in the work setting. In addition, the subject's work colleagues will be interviewed to obtain co-worker perspective on the impact of the HiRider in the workplace.

C. Seating Systems

[597] Computerized Shape Reproduction for Custom Contoured Wheelchair Seating Systems

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Sponsor: Cleveland Clinic Foundation Research Institute

Purpose—The medical necessity for custom contoured wheelchair seat and back supports has been widely

recognized in recent years. Until now however, the cost, accuracy of fit, and timeliness of fabrication have been

obstacles to widespread use of contoured supports. The objective is to apply computer technology to the shape-sensing and fabrication aspects of the dilatancy molding system.

Methodology—A shape sensor, consisting of a linear array of 32 potentiometers interfaced to an A/D board provides digital storage of seat and back contours developed in a simulator. Software has been developed for a 3-dimensional graphic display and on-screen shape modification. A modem transfers data from the molding session to a central fabrication site. Contours are then cut from polyethylene foam blocks after a subtraction software routine makes allowance for a soft foam liner. A PC-driven 3-axis milling machine is used for fabrication. The custom contours are then shipped to the therapist or DME dealer location for mounting in the mobility base. Shape fabrication can be accomplished in less than 1 hour with accurate results.

Results—A pilot study using the computerized shape reproduction system was conducted with 7 MR clients ranging in age from 14 to 28 years. Results to date are encouraging. Assessments were conducted to evaluate postural support and residual function with clients in the sitting position. Clients with varying disabilities including cerebral palsy, spina bifida, and spinal cord injury have been seated using this technique. Improved posture of the spine and upper body function were apparent without the loss of trunk stability. The reduction in peak interface pressures were added benefits of the contoured system with these clients.

Future Plans—The technology has been developed to the point where field-testing of the hardware and software is scheduled to begin. Continued data collection from field use will further demonstrate the benefits of contoured body supports.

[598] Development and Clinical Evaluation of an Adjustable Modular Postural Seating System for Persons with Mild to Severe Physical Involvement

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Sponsor: National Health Research and Development Programme, Department of Health and Welfare, Canada

Purpose—The purpose of this study is to develop and evaluate a cost-effective seating system that will interface with a wide range of available seating components, require few parts, and be easy to dispense with readily available tools.

The specific goals are to: 1) develop and evaluate a system of adaptable, pre-molded plastic shells; 2) develop and evaluate a foaming system compatible with the shell system; and, 3) prepare and evaluate a training package to assist seating clinics in dispensing the system.

Methodology—A working model of the core components of the pre-molded shells has been created. The system consists of a back pan, seat pan, and interfacing hardware.

Back shell. This component is a simple, one-piece, three-sided thermoformed pan made of ABS which is intended to be produced in three widths. The side panels and back height are oversized to enable customization of the pan by trimming. It is configured to locate between the uprights of the wheeled base. Inclination of the pan is provided by the interfacing hardware.

The back shell is secured by two sets of hardware. The upper set is semipermanently attached to the wheelchair push handles, and the lower set is attached to the back shell to avoid interference with the upright bushings as the chair is folded. To insert the back shell, the locking tabs on the lower clamps are released, and the torque knobs provided on the upper clamps are unscrewed. By pivoting the back about the upper clamp axis, the back shell can be removed.

Seat shell. This component is a molded ABS member with a lip on one side designed to friction-fit onto the rails of the wheeled base. It is provided with a 2-inch drop to avoid interference with the wheelchair cross bars.

Progress—Suitable interfacing hardware for securing the seat pans is currently under development. The seat shell is configured to accept commercially available cushions or polyfoam cushions. The simple polyfoam cushions will be made in predetermined sizes and upholstered. Provisions for adding a headrest and contoured laterals on the back shell and a footrest on the seat shell will also be made for the "next generation" prototype.

Future Plans—Once the shell arrangements have been finalized, a unique foaming procedure will be established for use with the system. After evaluation of the prototype design through clinical field trials,

assessment of instruction and training manuals will follow. The technology will be transferred to Variety Ability Systems Incorporated (VASI) for manufacture and distribution.

[599] Toward Development of a System for Safely Transporting Physically Disabled Children in Passenger Cars

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Sponsor: *National Health Research and Development Programme, Department of Health and Welfare, Canada*

Purpose—The purpose of this project is to provide protection, consistent with child restraint systems currently used in automobiles, for young children with physical disabilities. The specific goals are to: 1) develop a system for converting a commonly dispensed seating insert into a proven child restraint system; 2) create an education program to provide instruction to parents on the correct use of the system as a child restraint; and, 3) implement a quality assurance plan to ensure that a consistent level of system performance is achieved for the production version.

Physically disabled children often require specialized systems as a means for obtaining proper postural support and providing an opportunity for increased function. Available automobile child restraint systems offer insufficient support for many of these children. Therefore, parents often use the insert from the child's seating system for this purpose, although inserts do not provide adequate protection against automobile collisions.

Methodology—The system for converting a customized seating insert into a child restraint system consists of a triangulated, tubular frame, a restraint belt arrangement, insert interfacing hardware, and a tether strap. The struc-

tural component of the conversion system is an arrangement of tubular steel configured to rest on the car passenger seat and be the primary load-bearing structure responsible for "riding down" car deceleration. The frame provides anchoring points for the occupant shoulder harness, crotch belt, and tether strap. It is also designed to interface the postural support device to the passenger seat. The frame and seating insert are anchored to the car through the lap belt provided at that passenger seat location. The tether strap, which is anchored to the car body, is also included at the upper end of the frame to preclude excessive pitching of the restraint system and thus limit head excursion in the event of a motor vehicle accident or abnormal car maneuver.

The restraint belt distributes the impact forces over a large area of the child's body. The insert interfacing hardware is designed to isolate the securement of the child from that of the insert.

Future Plans—Impact tests will be conducted at the Downsview Civil Institute and Environmental Medicine Impact facility to verify the dynamic performance of the system. In addition, an education program will be developed to instruct parents on how to properly use the system.

[600] Functional and Clinical Evaluation of the Short- and Long-Term Effects of Anteriorly Tipped Seating in Children with Cerebral Palsy

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Sponsor: *National Health Research and Development Programme, Department of Health and Welfare, Canada*

Purpose—The objective of this study is to observe the effects of altered sitting positions on trunk stability, breathing patterns, and hand/arm function.

Methodology—The first part of this study compared functional parameters such as tidal volume, respiration rate, minute ventilation, trunk stability, and hand/arm

goal-directed velocity between a group of eight non-neurologically impaired (normal) children and a group of eight children with cerebral palsy, under different seating conditions.

The second part of the study examined the long-term effects of a 10-degree forward-tipped chairseat on 10 children with cerebral palsy. Following an initial assessment, adjustable tilting seats were provided for use by the children in a classroom for a period of 8 weeks, at which point the children were reassessed. During the following 8-week period, the children sat on their regular seats, after which they were assessed a final time.

Results/Implications—Short-term effects. Normal children exhibited a lower respiration rate than children with cerebral palsy in both the horizontal seat base and anteriorly-tipped seat base conditions. For the normal children, tilting the seat forward caused an increase in the respiration rate but a decrease in the tidal volume. The resulting effect was a decrease in minute ventilation. In

children with cerebral palsy, a tipped seat caused an increase in tidal volume which resulted in an increase in minute ventilation. It appears that forward-tipped seats facilitate increased diaphragmatic range of motion in children with cerebral palsy. Hand/arm targeting tests suggest that children with cerebral palsy use more space (move their hands over a longer path) in reaching for a specific target and require more time to do so, as compared to normal children. Although tipping the seat forward did not cause significantly improved targeting performance, clinical observations and a comparison of path patterns suggest that tipped seating may stabilize the trunk and improve upper extremity response efficiency.

Long-term effects. When tipped seating is used over a period of time, there appears to be a trend toward improvement of trunk stability, decreased tidal volume, and decreased minute ventilation for children with cerebral palsy. Forward-tipped adapted seating is regularly recommended and used successfully in a classroom setting for children with cerebral palsy.

[601] Development and Evaluation of an Advanced Pressure-Mapping System for Prescription of Seating Wheelchair and Positioning Systems

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Purpose—The clinician's capacity to provide advanced seating and positioning systems for disabled clients has grown enormously with the availability of sophisticated new commercial products and central fabrication capabilities. Custom-contoured and modular seating systems and advanced seat cushions are now being prescribed by large numbers of centers staffed by experienced clinical specialists. In many cases the process of positioning a client and defining the characteristics of the seating surface can be aided by the availability of a pressure-mapping system.

Currently, there are several pressure-mapping products available which measure the full wheelchair seat area. These systems are limited in their abilities to minimize error due to hammocking, to provide adequate spatial resolution, and to provide options to measure and record both peak and gradient pressures during functional activities.

The goal of this study is the development of a pressure-mapping system that promises a significant improvement in pressure-mapping technology. A device

developed for dental occlusion pressure-mapping (Tekscan Inc., Boston), offers great promise for application in the rehabilitation field. It employs the use of advanced computer-assisted lithography to produce a grid of over 2,000 sensors on centers 1 cm apart. The sensor area is 6 square mm; the thickness of the mapping system is 200 microns on a flexible mylar matrix. The sensing element is an advanced pressure-sensitive ink with excellent resilience and hysteresis properties. Preliminary work has demonstrated the potential for producing devices with a wide range of sensitivities to pressure by redesigning the electronic conditioning and altering the proportion of the conductive constituents of the ink.

This project will use this technology to develop an advanced clinical prototype pressure-mapping system, including both the hardware and software that would be used for seating clinic applications.

Final design criteria will incorporate recommendations from leading centers experienced in interface measurements. Performance and reproducibility of the Tekscan prototype and four commercial pressure measurement

systems will be contrasted against these ideal specifications and measurements compared on four cushions of different stiffness commonly prescribed for individuals with spinal cord injury. The prototype will also be tested by clinicians for prescription of cushions for clients at high risk for ulceration, for assessment of pelvic and body alignment and prescription of wheelchair inserts for postural support, and for dynamic measurements of impact loading during propulsion.

Progress—A survey of recommendations for design criteria of a wheelchair mapping system was returned from nine research and clinical centers in the U.S. and abroad. Performance and design criteria for the sensing pad, data management, cost, and durability were incorporated into initial prototype development.

We are in the process of building a pneumatic testing system and contoured loader gauge with electronic trans-

ducers for calibration and assessment of hysteresis, and effects of hammocking, curvature, and prominence on map performance. An initial wheelchair map and software system has been developed. Comparative bench testing and clinical trials have not been completed, but initial experience with the system indicates significant improvement compared to other systems. The map demonstrates high spatial resolution and appropriate measurement ranges. Data presentation includes options for real-time and freeze display of both a two-dimensional (2-D) pressure map and three-dimensional (3-D) pressure contour. Dynamic loading can be measured and recorded for 6 seconds and displayed in either 2-D or 3-D modes.

Future Plans/Implications—Complete testing and clinical evaluation of this system will determine potential for marketing as a seating clinic and research tool.

[602] Research and Development to Improve Seating Design

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Purpose—The purpose is to develop a new seating technology utilizing CAD/CAM for the improvement of tissue viability, body positioning, deformity management, comfort, functional ability, and mobility in wheelchairs and other seating devices. Specific objectives include: 1) study of tissue mechanics and physiology for the design of seating supports; 2) development of CAD/CAM custom seating systems for clinical application; 3) optimization of wheelchair seating, positioning, and propulsion; and, 4) information dissemination and technology transfer. The optimal goal is to provide cost-effective devices for the disabled.

Progress/Results—The work in progress and accomplishments are summarized as follows:

Magnetic Resonance Imaging (MRI) and Analytic Modeling of Weightbearing Soft Tissues. MRI techniques were implemented to quantify biomechanical properties and structure information of buttocks soft tissue in response to externally supportive loads for normal and SCI persons. The results showed that volumetric changes of fat and skin were greater than those of muscle under

compressive loadings, and T_1 relaxation times were found to be statistically different between loaded and unloaded soft tissues. Therefore, the T_1 time constant could be used as an index for characterizing loaded internal soft tissues and evaluating the cushion and support materials used in seating and bedding. A method was also developed to provide *in vivo* three-dimensional (3-D) geometric information for finite element modeling of the weightbearing buttocks. A nonlinear model has been developed that analyzes and predicts internal tissue deformation to correlate the results from MRI measurements. Work has continued to characterize the atrophic tissues of spinal cord injury and to verify validation of the analytic modeling process.

Evaluation of Custom Contoured Cushions (CCCs). An earlier prototype of the CAD/CAM seating system was used for both the research study and clinical seating service. In the past 12 months, more than 100 CCCs have been prescribed and provided for research subjects and clinical clients with different disabilities. The results have been encouraging for the continued development of custom seating technology. In addition, a study was conducted to

investigate geriatric seating and positioning, and the use of CCCs for nonambulatory elderly persons confined to wheelchairs. Twenty subjects over the age of 65 were randomly selected from a local nursing home. The information should be useful in identifying seating and positioning needs for the elderly. Custom seating and CCCs are likely to improve seating pressure, body posture, deformity accommodation, and comfort. Further clinical evaluation will center on cerebral palsy (CP) children and pediatric seating.

Design of CAD/CAM Seating Systems. A computer-aided shape sensing system using spring suspension has been developed for the determination of both custom seat contour and force distribution at the buttocks-support interface. This semiautomated system allows adjustment of individual sensor elements to prescribe the appropriate contour surface for different disabilities. A 3-axis carving system was also developed with the capability to fabricate seat cushions and back supports to a maximum depth of 8.5 inches for any surface dimensions that will fit within a 36-inch diameter circle. The system, which is controlled through a PC interface, consists of two translational and one rotary axis actuated by servo motors. Control of the axis is mediated by CNC cards installed in the PC. The time required to carve a typical wheelchair cushion is approximately 10 minutes. A comprehensive evaluation of the CAD/CAM system is being conducted at five selected rehabilitation centers for demonstration and future development of custom seating. Work is also continuing on an automated system for advanced seating technology.

Wheelchair Propulsion. This study was to investigate the biomechanics of levers and handrims for wheelchair propulsion and the effects of seat position and spinal cord injury (SCI) on propulsion mechanics. Six paraplegic and 9 able-bodied subjects were included for 3-D motion measures (trunk, shoulder, elbow, and wrist), hub torque and stroke arc measurements on 6 different seat positions. The joint torques were calculated from the data. Significant differences were found for changes in seat position and method of propulsion, and between able-bodied and SCI subjects. The results provide useful information for wheelchair design and seating prescription as well as development of analytic modeling for the optimization of wheelchair propulsion.

Wheelchair Seating and Positioning. In conjunction with the CAD/CAM seating system, a child's adjustable wheelchair has been designed for the development of modular and custom supports for disabled children. Work is continuing in the study of trunk support and the effects of body support and positioning on muscle activities and functional abilities in cerebral palsy children.

Technology Transfer. Custom seating technology has been successfully transferred to the South Carolina Rehabilitation Engineering Center (SCREC) for seating services, and to Pin Dot Products (Chicago, IL), a major manufacturer of specialized seating systems. Seat contours are measured in SCREC and transmitted via modem to UVA where the custom contoured cushion is fabricated. A CCC and cover are then shipped to SCREC. In the past 12 months, the system has functioned well and 28 clients with different disabilities have been provided with a CCC. A comprehensive beta evaluation of the UVA-REC CAD/CAM seating system is being conducted at five selected Centers: Newington Children's Hospital, National Rehabilitation Hospital, Helen Hayes Hospital, Rancho Los Amigos Hospital, and Texas Institute for Rehabilitation and Research. Pin Dot Products has also participated in all phases of this evaluation process for commercial development of the technology.

Recent Publications Resulting from This Research

- Biomechanics of Wheelchair Propulsion as a Function of Seat Position and User-Chair Interface. Hughes CJ, PhD diss., University of Virginia, 1990.
- Computer-Aided Shape Sensing for Prescribing Custom Contoured Seat Cushions. Sposato BA, Masters project, University of Virginia, 1990.
- Factors Affecting Seat Contour Characteristics. Sprigle S, Chung K-C, Brubaker C, J Rehabil Res Dev 27(2):127-134, 1990.
- Finite Element Model of the Human Buttocks. Todd BA, Thacker JG, Chung KC, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 417-418, 1990.
- An Investigation of the Load-Bearing Tissues of the Human Buttocks Implementing Magnetic Resonance Imaging. Protz PR, Masters thesis, University of Virginia, 1990.
- A Manufacturing System for Custom Contoured Foam Cushions. Brienza DM, Brubaker CE, McLaurin CA, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 415-416, 1990.
- Reduction of Sitting Pressures with Custom Contoured Cushions. Sprigle S, Chung K-C, Brubaker C, J Rehabil Res Dev 27(2):135-140, 1990.

[603] Research and Development on Assessing Wheelchair Ride Quality

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Purpose—A systematic method of evaluating the ride comfort for wheelchairs is needed to provide users with quantitative evaluation information. The development of new seating systems, suspension systems, frames, and tires require in the final analysis the methodology to assess the anticipated improvements in ride quality.

Progress—The reproducibility of the ride comfort data collecting system with the treadmill test configuration has been established. Software has been written to calculate means and standard deviations of the root mean square (RMS) acceleration data for a series of constant parameter tests. The averages and standard deviations of the acceleration frequency spectrum can also be calculated

from multiple tests. The results of the test show that the magnitudes of the standard deviations of the frequency spectrum stay below 10% of the mean values during severe tests. This indicates that the collection of data can be minimized and still see trends in the data. Initial floor data has been collected, but it was found to be very difficult to keep the speed at a constant value. It was also found that the rigid International Standards Organization (ISO) dummy data was totally different than the human body data. Finally, the wheelchair used for the tests only had elevated footrests, and did not represent the large population of wheelchairs with regular footrests. Invacare has recently donated a new manual wheelchair with regular footrests which will be used to collect more data.

[604] Development of a Tilting Backrest for Wheelchairs

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Sponsor: *The Rehabilitation Centre*

Purpose—The need for a good backrest-tilting mechanism arose from concerns voiced by seating clinicians. Research and development of a safe and easy system is ongoing.

Progress/Methodology—A positive spring-loaded locking mechanism is mounted on a set of square tubing

guides. The guides are fixed to the frame of the backrest, while two swiveling arms bridge the guides to the frame of the chair. A latching mechanism prevents the backrest from tilting accidentally. The system can be operated with one arm, and is now under evaluation.

[605] Biomechanical Analysis of Wheelchair Propulsion for Various Seating Positions

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Sponsor: *University of Ottawa*

Purpose—The purpose of this project was to investigate the propulsion of paraplegic persons for different seating positions.

Progress—The pattern of propulsion for five male paraplegics was investigated for six seating positions, consisting of a combination of three horizontal rear wheel positions

at two seating heights. To simulate wheelchair propulsion in the laboratory, the wheelchair was mounted on high rotational inertia rollers. For three trials at each seating position, the subject propelled the designed wheelchair at 60% of their maximal speed which was determined at the beginning of the test session. At each trial, the subject's propulsion technique was filmed at 50 Hz with a high-speed camera for one cycle; the raw electromyographic (EMG) signal of the biceps brachii, triceps brachii, pectoralis major, deltoid anterior, and deltoid posterior muscles were simultaneously recorded for three consecutive cycles. The digitized film data were used to compute the linear and angular kinematics of the upper body, while the EMG signals were processed to yield the linear envelope (LE EMG) and the integrated EMG (IEMG) of each muscle.

Results—The kinematic analysis revealed that the joint motions of the upper limbs were smoother for the low positions since they reached extension in a sequence (wrist, shoulder, and elbow) when compared to the high positions. Also, the peak linear acceleration of the hand at the end of the recovery phase was lower, thus facilitating the contact of the hands on the pushrims at the point of grabbing because lower acceleration would reduce slippage of the hands on the pushrims. Also, the forearm linear velocity slopes and the elbow angular velocity

slopes were less abrupt for the backward-low position. It was observed that in lowering the seat position less IEMG was recorded and the degrees of contact were lengthened. Among the seat positions evaluated, the backward-low position had the lowest overall IEMG and the middle-low position had the lowest pushing frequency. It was found that a change in seat position caused more variation to the IEMG for the triceps brachii, pectoralis major, and deltoid posterior. The trunk angular momentum was not found to be affected by a change in seat position which may be related to the variability among the subject's technique of propulsion or a posture compensation. Based on these descriptive observations it was concluded that the middle-low and the backward-low positions would be slightly better seating positions. Weak hip flexors are associated with class IV, and there is the possibility that some subjects adjusted their posture with a change of seat position.

Implications—The kinematic and EMG analysis of wheelchair propulsion at different seat positions has provided useful information to enhance our understanding and the development of wheelchair design. However, further studies should be conducted in this area to confirm our observations and to provide more information about the ideal seating position.

XVII. Wound and Fracture Healing

For additional information on topics related to this category see the following Progress Reports: [313], [377].

A. Pressure Sores

[606] Electrical Muscle Stimulation for the Prevention of Pressure Sores

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Purpose—Pressure sores represent a severe and costly problem for many disabled individuals, especially those who are wheelchair-dependent and have sensory loss. It was originally hypothesized by our group that electrical muscle stimulation (EMS) can help prevent pressure sore formation based on the rationale that: 1) tissue undulation produced from EMS (a “short-term” effect) will dynamically allow blood flow to ischemic areas; and, 2) the changes in vascular and muscle tissue produced from “chronic” EMS will lead to a reduction of pressure sores. This research program focuses on evaluation of short-term dynamic effects of EMS for pressure sore prevention.

Progress/Methodology—Work over the past 4 years on short-term dynamic effects of EMS for pressure sore prevention has demonstrated that: 1) EMS can reduce pressure under the ischial tuberosity in a seated individual with redistribution to other parts of the seating interface at very low stimulation intensities; 2) similar low-intensity stimulation of the gluteus maximus produces tissue undulation and shape reconfiguration of the buttocks under load; 3) EMS can produce increased muscle blood flow in seated individuals; and, 4) increased blood flow in skin and subcutaneous tissue can occur using EMS. Continuing work on EMS for pressure sore prevention has focused over the past year on small-scale, short-term clinical trials with newly spinal cord injured subjects.

For the most recent studies involving clinical trials with newly spinal cord injured subjects, a time series experimental design (A-B-A-B) was utilized. Phase A involved sitting with no EMS for a predetermined time, which produced redness under the ischial tuberosities that persisted for at least an hour following the sitting period. Phase B involved sitting for the same amount of time while EMS was provided via surface electrodes and a commercial stimulator. Parameters used to compare the EMS phase (A) versus the no-EMS phase (B) included skin temperature, size of erythematous area, and degree of erythema.

Results—The effects of extended sitting on skin erythema and temperature without any EMS were analyzed to serve as a baseline for comparison with EMS trials. Results showed a consistent skin temperature pattern after sitting with experimentally induced erythematous areas remaining elevated even after one hour of pressure relief. Results from seven subjects comparing EMS sitting trials with trials having no intervention showed a reduction in the area, intensity, and temperature changes of the erythematous area induced through extended sitting.

Future Plans—Results from this research program have provided a considerable amount of support for the use of EMS in pressure sore prevention. Multi-center outpatient trials of EMS for pressure sore prevention have been

proposed to and provisionally approved by the VA Rehabilitation Research and Development Service Evaluation Unit.

Recent Publications Resulting from This Research

Electrical Muscle Stimulation for Pressure Variation at the Seating Interface. Levine SP et al., J Rehabil Res Dev 26(4):1-8, 1989.

Electrical Muscle Stimulation for the Prevention of Pressure Sores: Tissue Shape Variation. Levine SP et al., Arch Phys Med Rehabil 71(3):210-215, 1990.

Blood Flow in the Gluteus Maximus of Seated Individuals During Electrical Muscle Stimulation. Levine SP et al., Arch Phys Med Rehabil 71(9):682-686, 1990.

[607] Enhancement of Wound Healing Using Synthetic Skin, Electric Stimulation and Hyperbaric Oxygen Therapy

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Sponsor: VA Rehabilitation Research and Development Service (Project #A447-RA)

Purpose—Decubitus ulcers, commonly referred to as bed sores, affect millions of Americans each year. They arise from prolonged bed rest and ischemia that occurs when areas of skin are compressed in weightbearing areas of the body.

Our group has been involved in evaluating several techniques to promote dermal and epidermal healing of bed sores. Previously, we have demonstrated that type I collagen in the form of flakes promoted healing of stage II and III bed sores in 85% of patients treated as compared to controls. The purpose of our current studies is to evaluate the use of collagen flakes containing hyaluronic acid and an aerosol form of collagen type I for treatment of bed sores.

Methodology—Five patients with chronic bed sores were treated with collagen flakes containing 1% or 5% hyaluronic acid while an additional five patients were treated with an aerosol form of collagen produced by Micro-Collagen Pharmaceuticals (Bangor, PA). All patients signed informed consent forms and were treated daily for 3 weeks prior to treatment with collagen using a standard protocol consisting of a daily saline wash, followed by application of a wet-to-dry gauze dressing. In cases where necrotic tissue was present, wounds were debrided prior to collagen treatment. The surface area was measured weekly by placing a clear plastic sheet over the wound and tracing the wound perimeter. After 3 weeks of treatment, the wounds were treated once a day using collagen flakes containing hyaluronic acid or a collagen aerosol spray after the saline washing step. Treatment was followed by the application of saline-wetted gauze and the dressing was secured to the surrounding normal skin

using adhesive tape. Wounds were treated with collagen for a total of 12 weeks.

Results—Results obtained in this study suggest that wounds treated with collagen flakes containing hyaluronic acid or a collagen aerosol showed healing that was similar to wounds treated with control collagen flakes. Some patients treated with collagen flakes containing 5% hyaluronic acid showed evidence of local hemorrhage within the ulcer. In comparison, wounds treated with collagen flakes containing 1% hyaluronic acid showed no evidence of hemorrhage and healed with similar kinetics to that reported previously for collagen alone. A 50% wound area reduction was observed in patients treated with collagen flakes containing 1% hyaluronic acid or the collagen aerosol over a time course of about 6 weeks.

Although collagen flakes have been shown to improve healing of bed sores, they are difficult to pack under skin flaps and often result in discomfort to the patient. Results of studies conducted using a collagen aerosol spray indicate that it offers advantages such as ease of application and reduced discomfort with respect to use of collagen flakes. In addition, reduction of the wound area observed with the spray is similar to that observed with the flake form of the material.

Implications—Our results indicate that initiation of healing of bed sores is promoted by type I collagen and is not further promoted in the presence of hyaluronic acid. Use of an aerosol form of collagen offers distinct advantages over flakes or other physical forms and results in comparable wound area reduction.

[608] Identification and Evaluation of a Comprehensive Skin Care Program to Prevent Skin Breakdown in Spinal Cord Injured Patients

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Purpose—The purpose of the study was to identify and evaluate a comprehensive skin care education program to prevent recurrent skin breakdown in patients with spinal cord injuries (SCI). A further purpose was to evaluate two methods of gaining the subjects' cooperation in practicing skin protection behaviors. Subjects in Group I received a behavioral intervention while those in Group II received a psychological intervention.

Results/Implications—A thorough review of existing skin care education programs revealed none adequate for the purposes of the study. A major problem was that the reading and comprehension levels required were too high. Thus, a skin care education program was designed and

produced as a low-literacy work book titled, *Your Skin: An Owner's Manual*. Copies are available from our Center.

Data are still being analyzed, but the following findings may be useful. Blacks and paraplegics with complete injuries are greatly over-represented in this population. Approximately two-thirds of the subjects showed evidence of cognitive impairment. Whether this existed before the SCI or was due to closed head injury at the time of the SCI could not be determined.

Although not statistically significant (the sample was too small), it appears that the behavioral intervention was more effective with this population than the psychological intervention.

The study was terminated in September, 1990.

[609] Treatment of Pressure Ulcers

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Development of improved clinical protocols may help reduce the staggering morbidity statistics resulting from pressure ulcers in people with spinal cord injury (SCI). In order to develop optimal active treatment protocols for pressure ulcers, basic wound-healing research is essential. The objectives of this study are to: 1) determine, in cell culture, the optimal concentration of oxygen and optimal pressure for fibroblast activation and macrophage deactivation; 2) determine, in cell culture, the optimal dosage of platelet derived growth factor (PDGF) to stimulate fibroblast activation; 3) determine, in rabbits, optimal use of oxygen for healing of both subcutaneous porous implants and full-thickness skin defects; 4) determine, in rabbits, the optimal dosage, timing, and type of growth factor drug delivery for healing of both subcutaneous porous implants and full-thickness skin defects; 5) test, in rabbits, the optimal oxygen therapy in combination with the optimal growth factor delivery systems for full-thickness skin grafts, and

full-thickness skin defects; and, 6) evaluate the efficacy of various therapeutic approaches on pressure ulcers in patients with SCI.

Methodology—The optimal concentration of oxygen and optimal pressure for fibroblast activation and macrophage deactivation will be determined by growing cells in a controlled environment at various predetermined combinations. The activation of cells will be determined by analysis of cellular metabolism, production of collagen (fibroblast), and cell growth. The optimal concentration of platelet-derived growth factor for cellular activation and deactivation will be determined by *in vitro* tests of cellular metabolism and cell growth. The PDGF exhibiting the greatest potential will be attached to polyactic and collagen matrices. The matrices will be tested in cell culture to determine the load of growth factor necessary to elicit increased cellular metabolism, collagen production, and cell growth.

Progress/Preliminary Results—During the first 24 months of the grant period, the following progress has been made: 1) primary cultures of fibroblasts and macrophages have been obtained from rabbits; 2) test results of the oxygen concentration and duration for fibroblast activation are in progress. Oxygen concentrations of 32% for up to 10 hours a day cause increased proliferation. Higher concentrations and/or durations of oxygen slowed fibroblast growth to below that of the control; 3) tests on the concentration of oxygen and duration for macrophage deactivation are still being analyzed. Initially, it seems to indicate decreased cellular proliferation with increasing oxygen concentration and duration of exposure; 4) tests using PDGF to increase the activity of fibroblasts are

on-going. Results at this time indicate that PDGF increases proliferation significantly in the 3-9 units/ml range—indicating that small amounts of PDGF produce significant increases in proliferation. No adverse effects of PDGF on fibroblasts proliferation have been determined; 5) test substances of collagen and collagen with PDGF have been tested *in vitro*. Collagen with PDGF has produced increased proliferation. Tests are on-going to determine the loading and attachment methods that are optimal; and, 6) *in vivo* testing of optimal oxygen levels on a rabbit model have been initiated.

Future Plans—*In vitro* testing will continue and *in vivo* testing will be initiated during this 5-year project.

[610] Use of Direct Current Stimulation in Pressure Sore Healing

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Purpose—A newly developed animal model for stage 3 or 4 pressure ulcers was used to study the influence of direct current (DC) stimulation on denervated wound healing. In two groups of animals, one group was treated daily with DC stimulation, while the other was used as a control.

Methodology—Changes in wound area, volume, perfusion, histology, and collagen were recorded as dependent variables. The exponential wound-healing model of Vodovnik and Stefanovska was used to calculate healing time constants. Results indicated reduced area and volume time constants in DC-stimulated animals, exceeding control values.

Results—Denervated tissue perfusion was estimated at the wound edge by measuring transcutaneous oxygen partial pressure. Healing tissues with or without stimulation showed greater than normal perfusion at the same anatomical sites. Stimulation initially reduced perfusion, then increased above and finally equalized with the unstimulated control site.

Histology showed a reduced inflammatory period followed by enhanced cellular proliferation with DC stimulation. Stimulation also induced earlier wound maturation. Histomorphometry, quantifying the vascular

density and cross-sectional area in the granulation tissue, showed advanced neovascularization with stimulation, significantly exceeding control values in the healed wounds.

There was no change in the collagen concentration of granulation tissue with applied DC stimulation. The concentration of hydroxyproline was the same in both the control and the stimulated tissues. Protein solubility tests also showed no significant increase in the soluble fractions of the DC-stimulated healed wounds.

Overall, the effect of DC stimulation was to enhance healing time constants and neovascularization without significantly affecting collagen synthesis of healed wounds.

Recent Publications Resulting from This Research

- An Experimental Pressure Sore Model for Functional Electrical Stimulation: Continuous Pressure Application on Monoplegic Pigs. Negami S et al., in *Advances in External Control of Human Extremities*, D.B. Popovic (Ed.). Nauka, Yugoslavia, 535-541, 1990.
- Orientation and Biomechanical Properties of DC Electrically Stimulated and Healed Pigskin Pressure Sores. Kambic HE et al., in *Advances in External Control of Human Extremities*, D.B. Popovic (Ed.). Nauka, Yugoslavia, 519-524, 1990.
- Wound Healing and Perfusion of Pressure Ulcers in Direct Current Stimulated Denervated Tissues. Reger SI et al., in *Advances in External Control of Human Extremities*, D.B. Popovic (Ed.). Nauka, Yugoslavia, 525-534, 1990.

[611] Therapeutic Intervention for Healing Pressure Sores with Electrical Stimulation on Persons with Spinal Discontinuities

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Sponsor: *National Institute on Disability and Rehabilitation Research; Commission of the European Communities, Directorate-General for Science, Research and Development, International Scientific Cooperation, Brussels; Research Communities of Slovenia, Ljubljana, Yugoslavia*

Purpose—The purpose of this project is to conduct a carefully controlled and quantified study on the effects of subthreshold tetanizing currents and a double blind study of the effects of DC currents on wound healing. Pressure sores in patients with spinal discontinuities and wounds due to peripheral vascular diseases are included in the study. Our purpose is also to find out the mechanisms by which electrical currents influence healing.

Progress—Subthreshold tetanizing and DC currents applied through skin electrodes are used. The first phase will address the problem of quantification and control. After the phenomenon is demonstrated with statistical significance, efforts will be concentrated on the mechanisms by which electrical currents influence healing.

Major efforts are devoted to the continuation of the clinical study which includes 60 patients with 90 decubitus ulcers, and 40 patients with wounds due to vascular diseases. All data are in a dBASE IV database, thus enabling simple access to relevant information and improved data processing.

Methodology/Results—In order to elucidate mechanisms which are involved in accelerated wound healing when electrical stimulation is applied, several basic studies have been started. Preliminary results seem to indicate that wounds to which AC pulses are applied heal twice as fast as control wounds, and somewhat faster than wounds treated with DC.

Endogenous skin potentials have been measured between wounded and normal skin on healthy subjects. It was found that the wounded area is positive relative to normal skin. During the healing process this potential difference slowly disappears.

Bacteriological analysis of samples taken from decubitus ulcers were performed. While the results for other bacteria are not quite consistent, it seems that electrical stimulation has a bacteriostatic effect on *pseudomonas aeruginosa*.

An *in vitro* study of effects of electrical stimulation on fibroblast proliferation and migration has been initiated. Since fibroblasts are responsible for most collagen formation, their role in wound healing is important.

Some additional techniques such as thermography, oxymetry, and magnetic resonance imaging (MRI) have been introduced. Preliminary data from thermography produced an interesting time course of temperature increase after electrical stimulation.

Recent Publications Resulting from This Research

- Restorative and Regenerative Functional Electrical Stimulation. Vodovnik L, Stefanovska A, in Proceedings of the Osaka International Workshop on Functional Neuromuscular Stimulation, J. Kawamura, T. Tamaki, K. Akazawa (Eds.), Osaka, Japan, 11-27, 1989.
- Accelerated Wound Healing of Lower Extremities by Means of Electrical Stimulation. Karba R et al., in Advances in External Control of Human Extremities, D.B. Popovic (Ed.), Nauka, Yugoslavia, 509-517, 1990.
- Database for Assembling and Analysis of Electrical Wound Healing Data. Kroselj P et al., in Proceedings of ETAN, Belgrade (in Slovene), 1990.
- Effects of Electrical Current on Healing and Bacteria Growth in Decubitus Ulcers. Karba R et al., in Proceedings of the 3rd International Symposium on Tissue Repair, Miami, FL, 1990.
- Pressure Sore Healing and Endogenous Potential. Jercinovic A, Bobanovic F, in Proceedings of the 10th Anniversary Meeting of Bioelectrical Repair and Growth Society, Philadelphia, PA, 1990.
- Self-Organization of Pathological Systems Induced by Electric Currents. Stefanovska A, Vodovnik L, in Proceedings of the 12th Annual International Conference, IEEE Engineering in Medicine and Biology Society, Philadelphia, PA, 1990.

[612] An Analytical Service Demonstration of the Role of Biochemical and Behavioral Indicators in the Prevention of Recurrent Pressure Sores

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Our purpose was to confirm the potentiality of a biochemical indicator to predict skin breakdown and the efficacy of specific self-directed behaviors to prevent recurrent pressure sores.

Methodology—This is an observational, prospective, cohort study. Males with spinal cord injury are randomly assigned to two groups. The control group will be interviewed only at the beginning and at the end of the study, and will provide a 24-hour urine sample at each of those times. The experimental group will be interviewed in person initially, and then by telephone every 4 to 6 weeks. They will provide a 24-hour urine sample at the time of each interview. Follow-up will continue for 2 years or until the subject develops a pressure sore, whichever comes first.

The interviews will elicit demographic information, medical history with special emphasis on incidence of pressure sores, and a description of the usual skin care regimen. The urine will be assayed for the content of glucosyl-galactosyl hydroxylysine, a collagen metabolite.

The data analysis will seek to establish the relative risk of developing a pressure sore based on the fluctua-

tions in urinary concentration of the collagen metabolite and/or specific items in the skin care regimen.

Progress—Recruitment of subjects has been completed. There are 40 experimental and 20 control subjects. Compliance continues to be good. Initially, 83% of the subjects believed they were not likely to develop a pressure ulcer within the year. At this time, 22% of the subjects have developed a pressure ulcer. Four subjects have completed the project with skin intact. Preliminary data analysis shows that a larger proportion of controls developed ulcers. Subjects with ulcers tended to be younger and had lower body mass index. The most frequently cited pressure ulcer prevention methods were: weight shifts, not sitting too long, skin inspection, and using the proper cushion.

Implications—Successful completion of this research project will provide a means of identifying patients at imminent risk of developing a pressure sore. More aggressive preventive measures can then be brought into play to forestall an actual skin breakdown. This should translate into a considerable reduction of hospitalization time and costs.

[613] Pressure Sore Prevention: An Effective Stepped Care Approach

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Purpose—The goals of this project include the refinement, validation, and dissemination of a novel system with unique potential to produce durable preventive behavior, and thereby lower the incidence and severity of ischial pressure sores. Its promise lies in its self-correcting, data-based approach; in its stepped, systematic application of a variety of interventions, both established and new; and in its utility in validating any effort at teaching pressure relief behaviors. The key to the

system is the Timer-Logger-Communicator (TLC), an electronic device developed by the authors. The TLC continuously and unobtrusively records pressure-relief behavior, and provides data, cues, or immediate feedback to enhance pressure relief behavior.

Progress/Methodology—To date, 45 subjects have been recruited, with five subjects currently enrolled. We are at 90% of our recruitment target and analysis of the data

collected to date is still in progress. All subjects have received standard teaching to prevent pressure sores as a baseline. If needed, experimental interventions were randomly

selected and applied. Engineering and software improvements have been made to the TLC, which is used to measure the timing and frequency of pressure relief behaviors.

[614] Bedsore Biomechanics

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Sponsor: *University of Akron; Edwin Shaw Hospital Foundation*

Purpose—Bedsore (pressure sores) or decubitus ulcers are localized areas of cellular necrosis resulting from prolonged excessive stresses on soft tissues, and present a major problem in the comprehensive rehabilitation of spinal cord injured patients and others with paralyzing neurological diseases. The type and magnitude of stresses generated in the tissue depend on body build, mechanical properties of the tissue, mechanical properties of the cushion, and posture, etc.

The objectives of this investigation are to study the effect of the following parameters on the internal stress distribution generated in the soft tissue of the buttock during vertical and inclined loading: 1) effect of bone and tissue geometry; 2) effect of mechanical properties of the soft tissue; and, 3) effect of the mechanical properties of the supporting cushion.

Progress—We have developed two types of 2-D physical models of the buttock. In each of these models, PVC gel simulating the soft tissue was cast around a wooden core simulating the bone. The first model had a rounded edge core to simulate blunt bony prominence. The second model consisted of a flat circular (sharp) edge "bone" core to simulate sharp bony prominences.

Each of these models was placed on a representative cushion and loaded. A grid etched on the "soft tissue" model allowed photography for calculating strains and stresses in the tissue. Cushion materials were compared in terms of the tissue-cushion interface pressure and shear stresses generated in the soft tissue.

In addition, we are developing interface pressure transducers using conductive polymers. We are in the

process of evaluating various types of polymers for suitability as interface pressure transducers.

Preliminary Results—Shear stresses generated in the model soft tissue were significantly larger in magnitude in the case of flat (sharp edge) bone core when compared to the rounded edge model. However, the compressive stresses in the flat (sharp edge case) were lower than the rounded edge model. There were significant stress concentrations in the case of the sharp edge model. Foam cushions led to more uniform stress distribution in the model soft tissue when compared to all others tested during vertical loading. The gel cushion performed better during inclined loading. Inclined loading led to large magnitudes of shear stresses in the buttock model when the model was supported by air and hydro cushions.

Future Plans—Currently, we are investigating the effect of aspect ratio (bone width to tissue thickness ratio) and mechanical properties of the soft tissue on the stresses generated in the soft tissue model during vertical and inclined loading.

Recent Publications Resulting from This Research

Stress Analysis of Cushion Supported Tissues with Respect to the Bedsore Problem. Candadai RS, Masters thesis, University of Akron, 1989.

Cushion Evaluation Based on Stress Distribution in Soft Tissues. Candadai RS, Reddy NP, Canilang EP, in Proceedings of the 13th Annual RESNA Conference, 403-404, Washington, DC, 1990.

Effects of Mechanical Stress on Lymph and Interstitial Fluid Flows. Reddy NP, in Pressure Sores: Clinical Practice and Scientific Approach, 203-220, D.L. Bader (Ed.). London: MacMillan Press, 1990.

B. Fracture Healing

[615] Enhancement of Union of Segmental Defect Fractures II

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Purpose—Application of rigid external fixators is a commonly accepted practice for stabilization of segmental defect fracture injuries. However, rigid immobilization of the fracture site greatly reduces the mechanical stimulus to which the bone is normally exposed. This environment is not optimal for osteogenesis.

The normal mechanical stimulus for osteogenesis in intact bone is intermittent cyclical deformation. Some studies have demonstrated that mechanical stimulation of the developing callous in the form of micromovement (1.0-2.0 mm) and/or loadsharing, results in earlier callous formation, callous with greater cross-sectional area, and an increase in fracture stiffness. However, the optimal temporal, distance, and stiffness parameters over which these mechanical stimuli should be restored to the fracture area have not yet been defined. Our goal is to define these parameters.

Progress—We are currently treating segmental defect fractures created in a canine model with the application of "variable stiffness" external fixators. These fixators allow both micromovement (up to 2.0 mm) and loadsharing (by weightbearing) in the callous area immediately after fixator application, thus ensuring a more normal frequency of axial loading during the healing period.

These devices have replaceable stainless steel springs; this allows us to customize the stiffness of the fixator to the weight of the animal.

Methodology—Forty-five adult mongrel dogs (50-60 lbs) are used. The dogs' radii are approached anteromedially and 2.50 cm osteoperiosteal segments are removed bilaterally, creating transverse diaphyseal defects. The defects in both legs are then supplanted with cancellous autogenous graft (generally accepted as the ideal bone graft material) from the contralateral humeral head. External fixators are applied bilaterally. One fixator has a 150 mm rigid stainless steel tube while the contralateral side has a 130 to 170 mm variable stiffness fixator. Dogs are sacrificed at 4, 8, and 12 weeks. Radiographs are

taken immediately postoperatively and at 4, 8, and 12 weeks depending on sacrifice. Following euthanization, both radii are excised and subjected to biomechanical testing by impact torsional testing. Afterwards, the bones are sectioned and stained for computerized video analysis.

Results—A small pilot project has been completed. Radiological results indicate that there are significant differences in cross-sectional areas between legs treated with variable stiffness fixators and control fixators. Additional histological and biomechanical data are necessary for conclusive results.

Future Plans/Implications—Use of these fixators will assist in determining the optimum osteogenic environment for segmental defect fracture healing by helping to define the precise relationships between the degree of fixator stiffness and micromovement, and the rates and patterns of fracture healing. These data will help to determine if the size and strength of callous formation are based on optimization criteria. Our hypothesis is that these results will allow us to *formulate a model of callous healing behavior under certain conditions of stress*. When applied clinically, this model could potentially result in a higher percentage of unions in segmental defect fractures by allowing some control over callous formation and remodeling. This would represent an inexpensive, practical method of treatment that could be utilized immediately with the use of currently available materials (i.e., AO clamps and Kirschner wires). Additionally, we are currently evaluating techniques for the Ilizarov method of bone transfer. Some trials are completed and the data will soon be evaluated. We have also recently completed a biomechanical study on synthetic graft substitutes which indicated that all of the synthetic graft materials were greatly enhanced by the use of aspirated bone marrow. A series of trials using a canine model to find the bone morphogenic fraction of bone marrow aspirate is scheduled.

[616] Periosteum as a Functional Membrane

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Sponsor: Cappagh Research and Development Trust

Purpose—The purpose of this study was to set up a periosteal membrane preparation for *in vitro* electrophysiological investigation. Clinically, periosteal membrane acts as a functional limiting membrane to bone formation. Under electron microscopy, the membrane structure shows tight junctions between apposing cells, and the size of the intercellular spaces seems to be influenced by calcitonin and PTH. The importance of the integrity of the periosteal and endosteal membranes has been emphasized by work on limb lengthening and bone transport.

Methodology—To obtain a sample of intact periosteal membrane free from muscle attachments, the outer table of the skull of mature Sprague Dawley rats was chosen as a suitable site. Under chloral hydrate anesthesia, two polyethylene washers are inserted subperiosteally and the membrane repaired over them. At 3 weeks, the animals are sacrificed and the skin and galea removed from the skull to expose the implanted washers covered with intact

periosteum. Both washer and membrane are removed together and placed in an Ussing chamber for electrophysiological determinations.

Results—The 3-week duration of implantation was chosen because the membrane is fully healed and bone has grown up through the core of the washer to reach the new position of the periosteum. Recorded potentials of the membrane are of the order of 500 microvolts and are difficult to separate from junctional potentials of the agar bridges. Transmembrane resistances of the order of $10^6/\text{cm}^2$ have been recorded between the two half-cells of the Ussing chamber.

Future Plans/Implications—It is proposed to use this model to investigate the effect of calcitonin and PTH on the transmembrane resistance of intact periosteal membrane. It may be a function of periosteum to control the ionic milieu and so act as a blood-bone barrier, as has been suggested by tracer studies.

[617] Enhancement of Femoral Head Fracture Healing by Means of AC and DC Electrical Stimulation

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Sponsor: Republic Ministry for the Research Activity and Technology of Slovenia, Yugoslavia

Purpose—The purpose of this study is to evaluate and compare the effects of DC and AC electrical stimulation on the healing of fresh femoral head fractures.

Numerous studies dealing with electrical stimulation of bone fractures have reported beneficial effects on healing, irrespective of the type of current (DC or AC) used. In our study, carefully selected and matched femoral head fractures of the same location will be immobilized and randomly assigned to four groups. Two experimental groups of patients will be treated with biphasic electrical stimulation, and with constant direct current of low intensity, respectively. The third group of patients will receive dummy stimulators (delivering no

current), and the fourth group of patients will serve as controls.

Finally, the comparison of healing times will provide the estimation of the effects of different treatment modalities, and will simplify making the choice of future clinical routine methods.

Methodology—Totally implantable current sources will be used for electrical stimulation. The stimulators are designed to deliver a defined current for a period of 10 months: after that, they will be removed. 1) *AC electrical stimulation*. Bipolar rectangular electrical current impulses with a mean value of zero, an amplitude of 25 mA, and

a frequency of 0.5 Hz will be delivered through Pt electrodes. These will be inserted in the bone marrow a few centimeters distant on both sides of the fracture. 2) *DC electrical stimulation*. Continuous direct current with the amplitude of $7\mu\text{A}$ will be used. The negative electrode (cathode) will be inserted directly in the fracture site. The positive electrode (anode) is attached to the stimula-

tor, which will be placed in the muscle tissue, 15 cm distant from the fracture. Actual current density utilizing Pt at the cathode will be $0.7\mu\text{A}/\text{mm}^2$.

Future Plans—The results of all experimental work carried out during 1990 will be gathered and analyzed during 1991.

[618] Biomechanics of External Fixation of Tibial Fractures

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Sponsor: *Scottish Home and Health Department, Chief Scientist's Office; Orthofix Srl., Verona, Italy*

Purpose—External fixation is a method of managing tibial fractures which offers the potential for studying and controlling the biomechanical environment in which the fracture is maintained. The aim of this project is to measure how this biomechanical environment changes as the fracture heals, to determine how this information can be used clinically, and to develop a system which can perform these measurements in a routine clinical environment.

Methodology—A strain-gauged transducer has been built into the fixator body to measure the six components of force and moment which it carries. Externally applied (ground reaction) forces and moments are measured using a Kistler force plate. Use of a VICON kinematic analysis system allows the effect of these forces at the fracture site, and the ratio of shared loading between the fixator and healing bone to be estimated. The data is analyzed for changes occurring through healing, and these are correlated with radiological and clinical observations.

Progress—A transducer-based system has been developed which is capable of giving estimates of the six components of load carried by the fixator, and applied externally during standing, walking, and certain clinical

tests. Thirteen patients have been monitored from initial application of fixator through to removal.

Preliminary Results—Several trends are suggested by results to date. Changes in the ratio of shared loading of the axial components of force give an early indication of the stability of the fracture and can be used to help determine the appropriate timing for dynamization.

Changes in the ratio of shared loading of bending moment components are observed later in the healing period and can give an indication of appropriate timing of the removal of such devices. Regular monitoring can give an early indication of pathological healing patterns.

Future Plans—More clinical evidence is required to confirm these results. It is intended to develop a microcomputer-based system to incorporate the findings of this study in a system which can be used routinely in the clinical environment.

Recent Publications Resulting from This Research

A System for the Measurement of Shared Loading Between Fractured Long Bones and External Fixators. Baker RJ et al., in *Proceedings of IMechE*, 165-170, 1989.

[619] Effect of Acetoazolamide on Fracture Healing

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Sponsor: *Department of General and Orthopaedic Surgery, University College Cork, Ireland*

Purpose—The purpose of this study was to investigate the hypothesis that alteration in the pH at the site of fracture healing might influence the rate of union. Fracture con-

solidation at the stage of calcification of the callus matrix is associated with a change in the pH of to an alkaline milieu. Patients with head injury and alkalosis often

generate excessive calcified callus at a fracture site. Acetoazolamide as an inhibitor of carbonic anhydrase would be expected to retard alkalization at the site of callus formation.

Methodology—A control and study group of Sprague Dawley rats were used with both groups subjected to a controlled tibial fracture which was internally fixed with an intramedullary fixation device. Both groups were managed postoperatively in similar fashion except that the study group was tube-fed with acetazolamide daily. Animals were sacrificed from both groups at regular intervals and the tibiae removed for analysis. All the tibiae were then tested in tension using an Instron tensile device after the intramedullary Kirschner wire was removed.

Results—The results suggest that fracture healing in both control and study groups proceeded in a similar fashion. Fracture stiffness and ultimate yield point remained at a low level for the first 3 weeks. In the fourth week, the stiffness of the control group was significantly greater than the acetoazolamide-treated group. At 6 weeks, both groups had fully united and showed no statistical differences in mechanical properties.

Future Plans/Implications—The specimens are presently undergoing histological analysis of matrix and mineral morphology to determine if differences exist to define the delay observed in fracture consolidation. The implication of this study is that it may be possible to accelerate the rate of fracture union by systemic alkalization.

C. Other

[620] Morphologic and Ultrasonic Analysis of Normal and Ischemic Human Wounds

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Sponsor: VA Rehabilitation Research and Development Service (Project #A210-2RA)

Purpose—We have engaged in the investigation of deficiencies in the wound healing process in individuals with peripheral vascular disease (PVD) and diabetes mellitus (DM). We hope to identify abnormalities in the repair process which may suggest clinical interventions.

Progress/Methodology—We have utilized standard incised wounds created with a Simplate II bleeding time device to produce uniform wounds on normal elderly subjects, as well as patients with PVD or DM who are awaiting amputation. A variety of time points following wounding have been evaluated and differences in events of repair defined for several variables including PVD, DM, transcutaneous pressure of oxygen ($TcPO_2$), and anatomic locations. We have also studied the timetable for the appearance and disappearance of a number of proteins thought to be important to the repair process, including thrombospondin, filaggrin, laminin, type IV collagen, $TGF\beta$, PDGF, PDGF receptor, SPARC and involucrins. Antibody to stain for

the presence of nonenzymatic glycosylation (NEG) of proteins has been successfully used to study human wound tissue. In addition to morphological and immunochemical evaluation of the repair process we have investigated the use of high frequency ultrasound as a method for noninvasive evaluation of the repair process. A scanning laser acoustic microscope (SLAM), and backscatter acoustic techniques have been used for the latter studies.

Results—We have now studied 24 patients with DM, 17 with PVD, and 25 normal elderly subjects. Morphological events of dermal repair are significantly advanced: 1) if $TcPO_2$ is greater than 21; 2) in the superficial wound compartment compared to the deep wound; 3) in controls compared patients with PVD and DM; and, 4) if arm wounds are compared to leg wounds. Epidermal events of repair were not different between controls, patients with PVD or DM. Wounds from diabetic patients stain much more intensely than normals for

NEG. Considerable progress has been made in the use of ultrasound to assess skin and wounds.

Future Plans/Implications—Using biochemical methods, we hope to be able to use our monoclonal antibody to the glucitolysine epitope (NEG) to identify the specific proteins stained in the diabetic wound matrix and to ascertain functional changes in these proteins which may be important in the pathogenesis of diabetic wound failure. We also plan to fully evaluate normal wounds and wounds from patients with PVD and DM for the presence of a variety of growth factor as well as a timetable for appearance and disappearance of those factors. We plan to use the validated human wound model to do comparative trials of growth factors applied directly to these standard wounds in dysvascular extremities.

[621] Diabetic Foot Ulcers: Quantifying the Effects of Nonsurgical Treatments

Roger E. Pecoraro, MD

VA Medical Center, Seattle, WA 98108; University of Washington, Seattle, WA 98108

Sponsor: VA Rehabilitation Research and Development Service (Project #A318-2RA)

Purpose—The purpose of this study was to describe the natural history of healing of diabetic foot ulcers and observe whether specific medical treatments might substantially improve the rate of healing. This required developing an objective method to quantitate the healing progress of cutaneous ulcers. We enrolled subjects and characterized them extensively with regard to aspects of their particular ulcer, status of diabetes, and a variety of physiological measurements, including nerve function and circulation. Patients were randomized to receive, in addition to standard treatment, intensive diabetes management for optimal control of diabetes, nutritional supplementation with zinc and ascorbic acid, and standard medical surgical treatment alone (control).

Methodology—Subjects who presented for treatment of lower extremity ulcers in the presence of diabetes were randomized prospectively to receive the various medical treatments identified above. Subsequently they were followed on a weekly basis in the outpatient setting with measurements which allowed calculation of the rate of ulcer healing. Subjects were followed until either total healing or an alternative definitive medical outcome such as amputation, osteomyelitis, requirement for surgical

Recent Publications Resulting from This Research

A Method for Localizing the Early Products of Nonenzymatic Glycosylation in Fixed Tissue. Kelly SB, Olerud JE, Witztum JL, Curtiss LK, Gown AM, Odland GF, *J Invest Dermatol* 93:327-331, 1989.

The Systematic Study of Partial Thickness Wounds in Normal Elderly Adults and Patients with Peripheral Vascular Disease (PVD) and Diabetes Mellitus (DM). Olerud J, Odland GF, Burgess E, Wyss C, Fisher L, Matsen F, presented at the Society of Investigative Dermatology, 1989.

Correlation of Tissue Constituents with the Acoustic Properties of Skin and Wounds. Olerud JE, O'Brien WD Jr, Riederer-Henderson MA, Steiger DL, Debel J, Odland GF, *Ultrasound Med Biol* 16:55-64, 1990.

Ultrasonic Assessment of Skin and Surgical Wounds Utilizing Backscatter Acoustic Techniques to Estimate Attenuation. Forster FK, Olerud JE, Riederer-Henderson MA, Holmes AW, *Ultrasound Med Biol* 16:43-53, 1990.

Ultrasonic Propagation Properties of Articular Cartilage at 100 MHz. Agemura DH, O'Brien WD Jr, Olerud JE, Chun LE, Eyre DR, *J Acoust Soc Am* 87:1786-1791, 1990.

revascularization, or death occurred. Vascular testing was performed on all subjects, including measurements of transcutaneous oxygen and carbon dioxide tensions, and segmental total Doppler blood pressures and toe blood pressures of the affected extremity. The rate of ulcer healing was quantified over a defined 4-week initial period of treatment, according to a method of tracing the ulcer contours sequentially and photography of the lesions.

Results—Over 100 diabetic individuals with foot ulcers were studied. A subgroup of 46 subjects who had full-thickness skin ulcers completed the protocol and characteristics of wound healing were described. Calculated rates of tissue repair were found to be from 10 to 50% as rapid as published rates for wound healing in people without diabetes. Overall, 83% eventually achieved reepithelialization with the remaining 17% failing to heal for a variety of reasons. Many factors were examined for the possibility that they might predict nonhealing. Particular demographic factors, specific aspects of diabetes such as type or level of glucose control, initial ulcer size, or presence of initial infection were not useful for predicting subsequent healing failure. Significant prediction of failure of tissue repair, however, was obtained by initial

measurements of transcutaneous oxygen and transcutaneous carbon dioxide at the periwound site. These measures of local skin perfusion appear to be much more sensitive and specific for predicting ulcer healing than traditional measurements of limb arterial blood pressure.

Recent Publications Resulting from This Research

Classification of Wounds in Diabetic Amputees. Pecoraro RE, Reiber GE, Wounds 2:65-73, 1990.

Dissociation of Skin Oxygenation from Arterial Blood Pressure in Diabetic Limb Amputation. Pecoraro RE, Reiber GE, in Proceedings of the European Association for the Study of Diabetes, Copenhagen, Denmark, 1990.

Pathways to Diabetic Limb Amputation. A Basis for Prevention. Pecoraro RE, Reiber GE, Burgess EM, Diabetes Care 13:513-521, 1990.

Tissue Repair, Clinical Outcomes and Associations with Healing Failure in Diabetic Foot Ulcers. Pecoraro RE, Ahroni JH, Stensel V, Diabetes 39(Suppl 1):157A, 1990.

[622] Bone-Derived Cells Produce a Chemotactic Factor

Dana T. Graves

Boston University Medical Center, Boston, MA 02118

Sponsor: National Institute of Dental Research, National Institutes of Health

Purpose—Monocytes arise from stem cells in the bone marrow, enter the circulation, and undergo final maturation to macrophages in peripheral tissue. Monocytes/macrophages are essential to wound healing as demonstrated by delayed or incomplete wound healing in animals depleted of monocytes. The inflammatory, proliferative, and regenerative phases of wound healing require the participation of monocytes/macrophages either through their phagocytic or secretory function. Particularly important is the secretion of growth-promoting factors which are capable of stimulating cellular proliferation and angiogenesis. Monocytes/macrophages may also support the growth of solid tumors through the production of paracrine and angiogenesis factors. Since the majority of monocytes/macrophages which infiltrate a wounded site or a solid tumor are recruited from the peripheral vasculature, factors which regulate monocyte chemotaxis are of considerable importance. The goal of this proposal is to study a monocyte chemoattractant, CF-O, produced by a cell line derived from an osteogenic

sarcoma. The proposed studies include deducing the complete amino acid sequence of CF-O through characterization of the CF-O, cDNA, studying transcriptional, translational, posttranslational, and secretory events in the production of CF-O, and describing its binding kinetics and stimulation of monocytes/macrophages. The constitutive synthesis of CF-O by a bone-derived cell line provides an opportunity to study a monocyte chemoattractant that may be important in osseous wound healing and in the growth of osseous tumors. This factor may provide insight into the potential control of monocyte chemotaxis by locally produced chemoattractants.

Recent Publications Resulting from This Research

Identification of Monocyte Chemotactic Activity Produced by Malignant Cells. Graves DT et al., Science 245:1490-1493, 1989. Mesenchymal Cell Growth Factors. Graves DT, Cochran DL, CRC Rev Oral Biol Med 1:17-36, 1990.

Expression of Transferrin and Vitamin D-Binding Protein Genes in Osteogenic Sarcoma Cell Lines. Adrian GS et al., Exp Cell Res (in press).

XVIII. Miscellaneous

[623] Development of a DHCP Database and Quality Assurance Information System for Audiology and Speech Pathology: A Pilot Study

Vernon D. Larson, PhD; Allen E. Boysen, PhD; James C. Malpass

VA Medical Center, Augusta, GA 30910; Audiology and Speech Pathology Service, VA Central Office, Washington, DC 20240

Sponsor: VA Rehabilitation Research and Development Service (Project #C979-PA)

Purpose—The purpose of this project is to assemble a databased and quality assurance information program on mainframe computers used in VA medical centers. Capitalizing on patient information usually entered into medical center computers, three additional and essential elements are required. These are: 1) the speech, hearing, or language problem presented by the patient; 2) the procedure applied in the assessment and treatment of the problem; and, 3) the assessment and/or treatment outcome.

Progress/Methodology—After soliciting end-user preference data and information from 10 VA medical centers, an alpha test version was constructed and developed. This version, written in MUMPS, is centered around problem codes (ICD-9) and procedural codes (CPT) and was released to four medical centers for testing. Based on user input, the design of the package was

enhanced and was made ready for beta testing. A reports package centering around patient visits, patient problems, and patient procedures has been implemented and has been found to complement a variety of recurring reporting requirements of Audiology and Speech Pathology Programs.

Ten medical centers have been selected to participate in a 60-day beta test. A review of the treatment-outcome literature in speech-language pathology has begun with the goal of making a judgment of the feasibility of uniform coding of treatment outcomes.

Future Plans—After the beta test has been completed, user information will be reevaluated and the package again modified. The electronic collation of data from the 10 beta sites will be a focus of the beta test. A review of the treatment-outcomes literature in audiology is planned.

[624] National Invitational Conference on the Development of a Health Services Research Capacity in Physical Disability and Rehabilitation

Gerben DeJong; Andrew I. Batavia, JD, MS

National Rehabilitation Hospital Research Center, Washington, DC 20010

Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This conference will assemble the leading researchers, consumers, providers, payers, and policy-makers who address issues concerning health services research (HSR) as it relates to the needs of disabled persons and the concerns of medical rehabilitation providers. The conference will: 1) identify and prioritize the leading HSR issues; 2) determine the adequacy of the current HSR capacity in disability and rehabilitation; 3) identify innovative approaches to the development of an HSR capacity in disability and rehabilitation; 4) make

recommendations on organizational approaches to the development of an HSR capacity; and, 5) make recommendations on the essential components of an HSR agenda in disability and rehabilitation.

Results—It is hoped that the conference will have assisted several agencies and foundations in setting their respective health services research agendas in the areas of physical disability and medical rehabilitation. Conference proceedings are now available.

[625] A Model for the Production of Low Demand Assistive Devices

William C. Mann, OTR, PhD; Joseph C. Mollendorf, PhD, MSME; Joseph Lane, MBA, MPA
Center for Therapeutic Applications of Technology, University at Buffalo, Buffalo, NY 14214

Sponsor: Office of Special Education Programs, U.S. Department of Education

Purpose—The value of assistive technology devices for persons with disabilities is widely acknowledged. However, the potential value of a device to an individual is not sufficient reason for the device to be designed, produced, and made available in the marketplace. Further, the more specialized the assistive device, the less likely it will ever be mass produced. Increasing the incentives for producing an assistive device will increase the likelihood that the device will be created, supplied, and supported. Increasing the economic incentives is not feasible for low demand devices, due to a lack of available resources and the inefficiency of tracking service provision for low demand items. The purpose of the University at Buffalo Applied Study Project is to direct incentives within the not-for-profit sector—universities and service agencies—to develop assistive devices.

Methodology—The Applied Study Model uses three elements to increase the availability of assistive technology devices: 1) existing technical knowledge (university faculty and service agency personnel); 2) available labor (students, consumers and faculty) compensated through non-profit systems; and, 3) existing fabrication resources (university workshop space). Within the model, consumers of assistive devices identified and referred by

service agencies and ongoing projects at the University of Buffalo, work with students in occupational therapy, engineering, and architecture enrolled in credit-bearing courses, to design and fabricate assistive devices that meet the needs of consumers. University workshops are used to fabricate the devices. Devices that appear to meet a broader set of needs will be made available for production by private corporations. The model includes a plan to establish a not-for-profit enterprise affiliated with the university and the private corporate community to sustain the project.

Within the model, participating departments offer an applied course on assistive technology for undergraduate and graduate students. The course involves student projects which design and produce assistive technology devices, for specific persons in need of an assistive device. Faculty with clinical experience and technical skills cooperate in directing student projects. The occupational therapy students bring clinical experience on human factors, the architecture students bring an understanding of design and environments, while the engineering students bring experience in materials, design, and fabrication. Students also conduct thesis research on assistive devices.

[626] Health Insurance Coverage of Disability Beneficiaries

Gerben DeJong; Andrew I. Batavia, JD, MS

National Rehabilitation Hospital Research Center, Washington, DC 20010

Sponsor: Social Security Administration, U.S. Department of Health and Human Services

Purpose—This study examined the disincentives to work associated with concerns of Social Security disability income (SSDI) beneficiaries who would lose their Medicare benefits and might not be able to obtain comparable employment-based health insurance benefits if they obtain gainful employment.

The objectives of the study were to: 1) develop a theoretical framework for deriving a greater understanding of the relationship between health insurance coverage and employment for SSDI beneficiaries; 2) examine the relationship between health insurance coverage of SSDI

beneficiaries and their decisions and capacities to seek, obtain, and maintain employment; and, 3) examine the private health insurance coverage available to SSDI beneficiaries, including gaps in coverage resulting from insurance exclusions, "pre-existing condition" clauses, and policy "riders."

Results—This 2-year study was completed September 30, 1990. Four existing data sets involving SSDI beneficiaries were analyzed: 1) the 1982 New Beneficiary Survey, conducted on behalf of the Social Security Administration;

2) the Survey of Income and Program Participation, conducted by the U.S. Census Bureau in stages since 1983; 3) the 1985 Louis Harris Survey of Disabled Americans, conducted for the International Center for the Disabled in cooperation with the National Council on the Handicapped; and, 4) the 1988 National Rehabilitation Hospital Survey of Persons With Severe Physical Disabilities.

During the first year, the project staff created SPSS work files with key variables to be examined using data tapes for each of the above sources of data; computed frequency distributions on all key variables; computed cross tabulations of outcomes by predictor variables; and performed factor analyses to identify data patterns that suggest groupings of variables to be further examined. In the second year, the project staff performed stepwise regression analyses on outcome variables (i.e., employment status and desire to work) on key predictor variables

(including various demographic factors and insurance coverage); constructed causal models; and tested models using linear structural relations programs, such as LISREL. The staff also examined a variety of different private health insurance plans to determine the adequacy of coverage for persons with disabilities.

Results from the preliminary descriptive statistical analyses indicate that the greatest disincentives are for persons who return to part-time work, as opposed to full-time work. Part-time workers are less likely to obtain the private health insurance they need when they lose public coverage through Medicare or Medicaid.

Implications—Part-time employment is often part of the transition from income assistance to full-time employment. Health insurance coverage for part-time workers is an important part of the bridge from SSDI to full-time work.

Section II

Sponsor Index with Selected Program Summaries

Part A. Department of Veterans Affairs

Rehabilitation Research and Development Service
810 Vermont Avenue, N.W.
Washington, DC 20420

Margaret J. Giannini, MD, Deputy Assistant Chief Medical Director for Prosthetics and Rehabilitation, Director, Rehabilitation Research and Development Service, Office of Clinical Affairs

The mission of the Rehabilitation Research and Development Service program is to improve the quality of life of disabled veterans by making them more functionally independent. This mission is advanced through ongoing research projects in such priority areas as prosthetics/amputation, spinal cord injury, and sensory aids. Areas of special emphasis include aging, physical fitness, and psychosocial rehabilitation (e.g., dementia, schizophrenia, Alzheimer's disease, etc.).

In the areas of prosthetics, amputation, and orthotics, VA sponsored researchers are continuing to test new materials and using computer technology such as CAD/CAM to develop a new generation of artificial limbs. For spinal cord injuries, the use of robotics continues to be studied, as does the possibility that computer-controlled electrical stimulation can be used to restore function to paralyzed limbs. Research projects in the area of sensory aids include the continuing development of advanced mobility aids for visually impaired people, digital hearing aids for those with hearing impairment, and various studies on treatment strategies and communication systems for aphasic individuals.

The Department of Veterans Affairs Rehabilitation Research and Development Service sponsors a national program to review proposals submitted by researchers in the rehabilitation field. The Scientific Review and Evaluation Board for Rehabilitation Research and Development and Ad Hoc members assess proposals for their scientific and technical merit, budgetary needs, and time requirements. In 1990, the Board reviewed 79 regular proposals. There were 35 research projects approved in the four general priority areas: 1) prosthetics/amputation/orthotics; 2) communication, sensory, and cognitive aids; 3) spinal cord injury; and, 4) aging. Ten pilot projects were reviewed, of which nine were approved to run for 1 year. Pilot projects are designed to test the feasibility of developing data, a technique, or a procedure prior to undertaking a regular research study.

VA Prosthetics Research and Development Center
103 South Gay Street
Baltimore, MD 21202
Husher L. Harris, Manager

Three units comprise the VA Prosthetics Research and Development Center: Office of Technology Transfer, Prosthetics Assessment and Information Center, and Rehabilitation Evaluation Unit.

Office of Technology Transfer
Jon S. Peters, Director (Acting)

The Office of Technology Transfer (OTT) is responsible for the dissemination of information on completed and ongoing results of rehabilitation research and engineering developments. OTT publishes the *Journal of Rehabilitation Research and Development (JRRD)*, *Rehabilitation R&D Progress Reports*, and a clinical supplement series to *JRRD*.

The *Journal of Rehabilitation Research and Development* is a scientific/engineering quarterly publishing original research in rehabilitation. Supplements based on need and interest in the areas covered by *JRRD* and presented in a format appropriate for the clinician/practitioner are also published. The annual *Rehabilitation R&D Progress Reports* is a compilation of summaries by investigators on the status of their current research. Portions of OTT publications are available electronically through the VA Rehabilitation Database on CompuServe.

Prosthetics Assessment and Information Center
Ronald I. Lipskin, Director

The mission of the Prosthetics Assessment and Information Center (PAIC) is to evaluate commercial rehabilitation products, develop product standards on safety and performance, and to facilitate the delivery of rehabilitation technology directly to disabled veterans and to the clinicians who care for them.

During Fiscal Year 1990, PAIC completed evaluations of 40 commercial products. Reports were submitted to the VA Marketing Center for formal action through the Prosthetic Technology Evaluation Committee (PTEC) in the Department of Veterans Affairs Central Office.

Standards development activities are well along on manual and powered wheelchairs. PAIC plans to focus on identifying levels of performance acceptability for VA procurement purposes and validation of testing procedures as defined in the documents prepared by RESNA for submission to the American National Standards Institute (ANSI).

The Clinical Interface Program (CIP) continues to provide technical support to veterans and clinicians in the immediate geographical area. But, during Fiscal Year 1990, the CIP has been increasingly directed to product development. Among the working models that were fabricated and are now under clinical review are a weighted walker, powered elevating legrests for wheelchairs, and a powered mobile prone stander.

Rehabilitation Evaluation Unit

Saleem J. Sheredos, Director (Acting)

The mission of the VA Rehabilitation Evaluation Unit (REU) is to oversee the introduction of, promote the use of, and foster the availability of new devices and techniques to optimize the rehabilitation of physically challenged veterans.

REU's goals are to: 1) screen ongoing rehabilitation research and development, primarily sponsored by the Department of Veterans Affairs Rehabilitation Research and Development Service (RRDS), to identify products or techniques that are ready for transfer from research and development to clinical application, for which the VA has an identified need; 2) coordinate clinical application studies away from the R&D arena on the selected products and techniques to affirm their application in treatment programs; 3) foster the commercial availability of successful products by helping to overcome the barriers faced by potential manufacturers; and, 4) widely disseminate clinically useful information to professionals who effect the rehabilitation of disabled veterans.

When a development (technique or device) is identified as completed, a Request for Evaluation (RFE) is prepared in accordance with VA Circular 10-87-32 and forwarded to the Director, REU at 103 South Gay St., Baltimore, MD 21202. The RFE must be sent over the signatures of the R&D principal investigator(s) (PI), the Associate Chief of Staff for Research and Development (ACOS/R&D), and the Director of the VA Medical Center funded for the R&D effort.

An addendum to this procedure (called an RFE INTENT) is currently being tested. This document is intended for use when the development is within 12 months of completion. It is prepared according to the same requirements of the RFE, except that it requires only the PI's signature, with a copy going to the ACOS/R&D. This procedure was initiated to aid the timely review and budget plans for the potential field study which should lead to a commercial product or an effective procedure for clinical use.

Once the RFE is received, it is nominally reviewed by three experts on the readiness and current value for clinical application, which leads to recommendations for a field study, or the need for further development, or project termination.

For an approved RFE, a field study is designed and implemented by the Director, REU, as the evaluation's PI who collaborates with the R&D PI(s) and the appropriate VA Central Office (VACO) Service Director(s), with approval of the Director, RRDS. Field-participating investigators are designated who coordinate the local clinical trials. The Research and Development PI is a consultant (generally at no cost) to the study, while VACO Service Directors are administrative collaborators in accomplishing the study.

REU coordinates the evaluation, collects the data, performs data analysis, issues progress reports (using SPSS software), and prepares the final report with specific recommendations.

During 1990, REU worked on the following projects:

1. Synergic Prehensor
2. CP Skin (Seattle Skin)
3. Handbike
4. Adaptive Digital Hearing Aid
5. Ultrasonic Head-Controlled Wheelchair
6. APL/Dankmeyer Above-Elbow Powered Prosthesis
7. Unistik Controller
8. Wheelchair Aerobic Fitness Trainer (WAFT)
9. FES/Pressure Sores
10. Rectal Probe Stimulator
11. VA Seattle Below-Knee Prosthesis
12. Back Analysis System
13. MYO Beeper
14. Modular Electromechanical Lock Actuator
15. Development of Advanced Body-Powered Prosthetic Arms

The following are reports at the two Rehabilitation R&D Centers and the Rehabilitation R&D Unit.

Rehabilitation Research and Development Center

**Edward Hines, Jr. Hospital, Department of Veterans Affairs
Hines, IL 60141**

John Trimble, PhD, Director

The VA Hines Rehabilitation Research and Development Center has been very productive throughout fiscal year 1990 with new and exciting developments in research, product development, and technology transfer.

We have reorganized our research program into three inter-related sections to take better advantage of our clinical and academic environments. The new sections are Musculoskeletal Disorders, Rehabilitative Neurosciences, and Applied Exercise Science and Health Promotion.

The Musculoskeletal Disorders Research Section focuses on spine disorders and on degenerative joint disease. Studies within this Section involve determining how musculoskeletal disorders, especially spinal disorders, lead to disabilities; establishing methods for assessing the extent of these disabilities; devising methods for preventing such disorders; and developing improved treatment modalities.

The work of the Rehabilitative Neurosciences Research Section focuses on improving or restoring the motor control of persons with spinal cord injuries. The studies within this Section focus on techniques for neural regeneration, neuromuscular electrical stimulation, and treatment of micturition dysfunction.

In the Applied Exercise Science and Health Promotion Section, research focuses on the health and fitness of persons with mobility limitations. Research in this Section includes studies on assessing and maintaining the cardiovascular fitness of people with mobility limitations and studies on improving the cardiovascular fitness of people with disabilities.

We have broadened our research program by increasing our extramural collaboration. In the last year, we developed several significant research initiatives with the Harry G. Armstrong

Aerospace Medical Research Laboratory, Department of the Air Force, and the U.S. Office of Naval Research. Our new collaborative projects include studies on the use of three-dimensional sound for orienting blind people, development of a force-reflecting joystick, and the development of new types of implantable electrodes.

We have expanded our collaborative research efforts with the private sector. Over the past year, we have initiated research projects with AcroMed Corp., Baxter Healthcare Corp., Hollister, Inc., and Howmedica Corp. These efforts should contribute substantially to our mission of transferring our research results to the private sector.

We have also expanded our research program by strengthening our ties with universities. Our unique satellite research and develop program at the University of Illinois at Urbana-Champaign (UIUC) is the most noteworthy of our academic programs. Six collaborative projects have been developed between the Center's staff and the UIUC faculty although the program is only in its first year of operation. We expect that many of these projects will develop into Merit Review proposals to the Department of Veterans Affairs and other funding agencies.

Our Technology Development Program has also grown by developing senior design programs with UIUC and by developing a mechanism to feed these design programs with input from people with disabilities. We have also expanded our Technology Development Program by adding student projects on market analysis and commercial feasibility of new products for people with disabilities.

These initiatives hold great promise for growth and productivity in the coming decade. Through them, the Rehabilitation R&D Center at VA Hines Hospital will continue to be a significant resource for research on disability-related problems and the development and commercialization of enabling technologies.

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Rehabilitation Research and Development Center VA Medical Center

Palo Alto, CA 94304-1200

Felix E. Zajac, PhD, Director

The Palo Alto Rehabilitation Research and Development (RR&D) Center, in affiliation with the Schools of Engineering and Medicine of Stanford University, is dedicated to developing new state-of-the-art technological aids and treatments for disabled and infirm veterans. To accomplish this objective, we perform basic and applied research essential to the development of new aids and treatments, design and develop rehabilitation devices and methods, and foster the growth of the rehabilitation field through education.

The mission of the RR&D Center in the next 5 years will be to improve the quality of life of veterans with limb disabilities by designing new devices and methodologies. We will accomplish this mission by working towards three goals: 1) preserving limb function, in face of existing or threatening limb disabilities; 2) restoring function which is impaired owing to limb disabilities; and, 3) replacing function lost by limb disabilities.

Accomplishing these goals will improve the quality of life of limb-disabled veterans by increasing their independence, upgrading their competence in activities of daily living, and enlarging possibilities for their occupational and vocational rehabilitation.

The following two examples illustrate the importance of limb function as a focus of concentration. First, traumatic injuries often lead to disabilities in multiple limbs (quadriplegia), single limbs (amputations), or partial limbs (nerve, tendon, and bone damage). Rehabilitation may begin with surgical intervention (nerve repair, tendon transfer, joint replacement) and may continue with techniques such as functional neuromuscular stimulation. When restoration is suboptimal, application of robotics may replace lost function. Second, elderly patients frequently have multiple disabilities including vision impairment, nerve damage, amputation, and arthritis. In such a patient, preservation of remaining function by the prevention of falls, restoration of function through joint prostheses, and replacement of function by use of tactile computer interfaces, will all contribute to increased independence and better quality of life.

The RR&D Center is organized around three sections of investigators: the Neuromuscular Systems (NMS), Orthopaedic Biomechanics (OBM), and Human Machine Integration (HMI) Sections. Sometimes these sections work separately, at other times they work together to accomplish subgoals associated with each of the three main goals (i.e., the preservation, restoration, and replacement of limb function in disabled veterans). To assure that new rehabilitation devices and methodologies reach the disabled veteran as soon as possible, the Technology Transfer Section is engaged in establishing and conducting an energetic program for the continual transfer of products and techniques developed by the three investigator sections (HMI, NMS, OBM). The Technical Support and Administrative Support Sections support the research and development projects and the technology transfer activities by assuring the efficient operation of the RR&D Center in meeting VA regulations and providing liaison with the Palo Alto

VA Medical Center and the Department of Veterans Affairs Central Office operational services (e.g., Fiscal, Supply, Research Office, RR&D Service).

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Atlanta Rehabilitation Research and Development Unit VA Medical Center

Decatur, GA 30033

Franklyn K. Coombs, Director

The Atlanta Rehabilitation Research and Development Unit primarily conducts research into the problems associated with the loss of independence, mobility, and health status of older people. Although "Aging" is the central unifying theme of the Unit, research into problems affecting disabled people in general are also pursued. The Unit is composed of three discipline-oriented branches: Engineering and Computer Sciences, Physiological Sciences, and Sensory and Behavioral Sciences. Problems are addressed from a multidisciplinary perspective with input from each Unit branch.

The mission of the Atlanta Rehab R&D Unit is twofold: first, to understand by knowledge gained through research, the problems, capabilities, and needs of elderly and/or disabled veterans that impact on their functional independence and quality of life; and, second, to apply those understandings to the development and utilization of concepts, technologies, and devices to further functional independence and quality of life for the elderly and/or disabled veteran.

To achieve these goals, the Unit conducts research into problems associated with the loss of independence, mobility, and health status, which may include the collection and analysis of normative data on older people's decremental loss of function. The accomplishment of these goals will include development of new and/or unique concepts, techniques, and devices for rehabilitation. An important component of the

overall Unit plan is the dissemination and implementation of research results and developmental programs. Included in this objective is the transfer of technology to the private sector, which may include the commercialization of techniques and devices.

The Atlanta Rehab R&D Unit conducted many strategic planning sessions, culminating in an evaluation of the strategic plan at a meeting in Callaway Gardens, GA, which included national representatives in the field of aging. The recommendations from the Callaway meeting were to address five major areas as programs of research: musculoskeletal; sensorimotor; cognition; wellness and health maintenance; and, safety and mobility. These five programs of research were further divided into subprograms. Each subprogram will be implemented with a series of pilot studies and Merit Review funded projects. These programs of research and subprograms were selected over other areas in aging because 1) each has a rehabilitation component; 2) the Unit has expertise in the area; and, 3) the initiatives listed were not duplicating studies elsewhere. The five programs and subprograms will be phased into operation as staff and resources become available.

The Unit conducted 13 merit approved research projects during fiscal year 1990.

The Unit conducted 14 Core-supported pilot studies in 1990. The purpose of the pilot studies was to obtain preliminary data to facilitate development of high quality Merit Review applications. Titles of pilot studies conducted this year were:

1. A Pilot Study to Evaluate a Joy Stick Box Retractor for Powered Wheelchairs
2. A Pilot Study for the Design and Evaluation of a Safe Outrigger for Monoskiing
3. The Evaluation of Lower Limb Amputees for Functional Prosthetic Use: The Role of Objective Cardiac Testing
4. A Modular Composite Orthotic System: Development and Clinical Evaluation
5. Mobility Assistance: A Training Video Tape—Topics for Working with Multiply Impaired Persons
6. Accidental Injury of the Elderly at Home: A Pilot Study
7. Evaluation of Four Different Toilet Room Grab Bar Configurations
8. Assessment of Independent Living Skills for Elderly People with Impaired Vision
9. Design of a Radiotranslucent Chair for X-ray Analysis of Dysphagia
10. Development of Extended Norms for the Wechsler Adult Intelligence Scale—Revised (WAIS-R) and Dementia Rating Scale (DRS)
11. Dynamic Posturography in Elderly People
12. Balance Training in Stroke Rehabilitation
13. Magnetic Stimulation of Focal Brain Sites
14. Development and Validation of a Physical Exercise Inventory

Laboratory Resource Developments

A number of laboratory resources are available at the Atlanta Unit:

The *Vision Assessment Laboratory* provides support for research in visual perception and visual function. Equipment

on hand includes devices for measuring dynamic and static visual acuity, visual fields, sensitivity to contrast, oculomotor function, and distance and depth perception. Several innovative measures of accommodative response, distance and depth judgments, and contrast sensitivity are currently being used to compare visual function and performance between younger and older individuals who have no organic pathology.

The *Digital Design Laboratory* contains equipment to design, debug, and test digital and microprocessor circuits and systems. The equipment covers the entire design process from design and verification to software execution profiling.

The *Computer-Aided Design Facility* contains a CAD workstation for both electronic and mechanical design, which is also used for producing line drawings of circuits and mechanical assemblies.

The *Psychoacoustics Laboratory* includes test apparatus for pure tone sensitivity, free-field sound localization, and detection of sound shadow. Studies are also being conducted in this laboratory to determine echolocation and spectral shape.

The *Video Analysis Laboratory* permits behavioral researchers to obtain detailed and accurate observational data through the use of video tape. Relevant data are edited onto composite tapes and events of interest are evaluated by at least two observers to obtain inter-rater reliability.

The *Vestibular Laboratory* houses a *NeuroCom* Balance Test System which is used to evaluate both patients' and research participants' balance problems. The balance test system is a key evaluation device for falls and mobility dysfunctions in older people.

The *Instrument and Machine Shop* is available for the fabrication of mechanical pieces and assemblies needed to support individual research projects.

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National Institute on Disability and Rehabilitation Research
U.S. Department of Education, 400 Maryland Avenue, SW, Washington, DC 20202-2646

The National Institute on Disability and Rehabilitation Research (NIDRR) is part of the Office of Special Education and Rehabilitative Services (OSERS) in the U.S. Department of Education. NIDRR contributes to the independence of persons of all ages who have disabilities by seeking improved methods, systems, products, and practices involved in the rehabilitation process. It does this through grants, contracts, and cooperative agreements with states, universities, Indian tribes and tribal organizations, companies, and individuals. Recipients of funds range from graduate student fellows to university consortia. Information on all NIDRR-funded projects is published annually in the "NIDRR Program Directory." Copies may be obtained by writing to the address above or calling (202) 732-1184.

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National Institutes of Health

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National Research Council of Canada

Institute for Intelligent Systems, Ottawa, K1A 0R8 Ontario, Canada

S.A. Mayman, Director General

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National Science Foundation

1800 G Street NW, Washington, DC 20550

Erich Bloch, Director

The Bioengineering and Aiding the Disabled Program of the National Science Foundation (Room 1132) provides funding for biomedical engineering research directed toward the characterization, restoration, or substitution of normal physiological function. The emphasis is on fundamental research that will support the emergence of new technology.

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Natural Sciences and Engineering Research Council of Canada

200 Kent Street, Ottawa, K1A 1H5 Ontario, Canada

Dr. Arthur May, Director

The Natural Sciences and Engineering Research Council is Canada's largest research granting agency. While it does not target its research directly in the area of rehabilitation, the council does fund research in the engineering of prosthetic devices and artificial limbs, as well as computing, communications, and instrumentation technology.

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Nederlands Comite Kinderpostzegels

Delft, The Netherlands

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Netherlands Organization for Research Foundations for Biophysics and for Biological Sciences

Amsterdam, The Netherlands

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New York State Science and Program and Technology Foundation (Technologies and Disabilities Program)

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Nijmegen Institute for Cognition Research Information Technology

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Ontario Mental Health Foundation

Toronto, Ontario, Canada

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Ontario Ministry of Colleges and Universities

Ontario Research Incentive Fund, Toronto, Ontario, Canada

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Ontario Ministry of Health

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Ontario Ministry of Transportation and Communication

1201 Wilson Avenue, Downsview, M3M 1J8 Ontario, Canada

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Paralyzed Veterans of America, Spinal Cord Research Foundation

801 18th Street, NW, Washington, DC 20006

R. Jack Powell, Executive Director

The Spinal Cord Research Foundation (SCRF) was originally founded by the Paralyzed Veterans of America in 1975. SCRF sponsors research projects and fellowships in the basic sciences (neuroanatomy, neurophysiology, urinary, cardiopulmonary) that are designed to increase scientific knowledge of spinal cord injury and dysfunction. SCRF also funds research in clinical, technological, and psychosocial areas of importance to persons with spinal cord injury or dysfunction.

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Physicians' Services Incorporated Foundation

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Poona District Leprosy Committee

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J.M. Mehta, Hon. President

Poona District Leprosy Committee has been supporting and carrying out research in the field of medical and socio-economic rehabilitation of leprosy patients with special reference to reconstructive surgery for the correction of leprous deformities, causes, pathogenesis and prevention of such deformities, and related clinical application.

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The Region of Lombardy

Milano 20148, Italy

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Republic Ministry for Research Activity and Technology of Yugoslavia

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Research Communities of Slovenia

Ljubljana, Yugoslavia

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Rocky Mountain Regional Spinal Injury System

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Royal Ottawa Health Care Group

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USING THE EXISTING VA REHABILITATION DATABASE ON COMPUSEVE

I. What you need: Access to equipment and software.

- Personal computer
- Modem with communication software
- Subscription to CompuServe (connect time costs range from \$6/hour [300 baud] to \$12.50/hour [1200 baud], prices vary with baud rate).

II. You can get help if needed:

- VA Rehabilitation Database – write or call
Dori Grasso
Office of Technology Transfer (110A1)
VA Prosthetics R&D Center
103 South Gay Street
Baltimore, Maryland 21202
Phone: 301-962-1800

III. The VA Rehabilitation Database is user friendly:

- A user friendly system is a central design feature of the database. No previous experience with computers is necessary and very little learning is required. The system makes obtaining information about rehabilitation devices as easy as making a telephone call.

IV. Eligibility:

- The VA Rehabilitation Database is available for use by anyone who subscribes to CompuServe.

V. Free/discount services:

- The Office of Technology Transfer (OTT) can assist new users in obtaining limited free CompuServe time as an introductory service.

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